

Historic, Archive Document

Do not assume content reflects current scientific knowledge, policies, or practices.

2151975
U538

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

USDA
NAT'L AGRI. LIBRARY
2003 JUL 18 10:47
CENTRAL
WASHINGTON, DC

FSIS DIRECTIVE

5000.1
Revision 1

5/21/03

Verifying an Establishment's Food Safety System

I. PURPOSE

This directive issues FSIS Handbook 5000.1, Verifying an Establishment's Food Safety System. This handbook provides comprehensive direction to FSIS field personnel on how they are to protect the public health by properly verifying an establishment's compliance with the pathogen reduction, sanitation, and HACCP regulations.

II. CANCELLATIONS

FSIS Directive 5000.1, Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations

FSIS Directive 11,000.1, Sanitation Performance Standards

FSIS Notice 28-02, Actions to be Taken in Establishments Subject to *Salmonella* Testing

III. REASON FOR REISSUANCE

This directive has been rewritten in its entirety as a handbook that also combines instructions from FSIS Directive 11,000.1 and FSIS Notice 28-02. The new handbook provides one comprehensive source for Consumer Safety Inspectors (CSIs) and Consumer Safety Officers (CSOs) to use when verifying or assessing an establishment's food safety system.

IV. REFERENCES

9 CFR parts 416, 417, and 500
9 CFR 310.25 and 381.94

DISTRIBUTION: Inspection Offices; T/A Inspectors;
Plant Mgt; T/A Plant Mgt; TRA; ABB; TSC, Import Offices

OPI: OPPD

V. ATTACHMENTS AND FORMS

Attachment 1--- Handbook 5000.1, Verifying an Establishment's Food Safety System

FSIS Forms 5000-1 through 5000-4 (Available on FAIM)

VI. BACKGROUND

The attachment, Handbook 5000.1, is designed to assist CSIs and CSOs in performing, and in better understanding, their job responsibilities. It includes, at the beginning, tables that CSIs can use to find in the Handbook the verification procedures, documentation instructions, and enforcement actions for specific activities codes. To facilitate use of this Handbook, the following walk-through is provided.

A. How do CSIs and CSOs use the Handbook and tables for the Sanitation Performance Standards (SPS) regulations?

CSIs perform the 06D01 procedure when verifying an establishment's compliance with the SPS regulations. For a brief description of how to perform the 06D01 procedure, CSIs should refer to pages I-3 and I-4 of Handbook 5000.1. When a CSI is to perform an 06D01 procedure, the CSI may wish to review pages I-3 through I-21, of the Handbook, to ensure that he or she is familiar with all of the SPS regulatory requirements. Once the CSI is familiar with all the SPS regulatory requirements, he or she will determine which requirements to verify while performing the 06D01 procedure. The CSI can use any method for determining which regulatory requirements he or she plans to verify. The CSI should verify all of the SPS regulatory requirements on an on-going basis. The CSI should coordinate the frequency with the Front-line Supervisor. The Front-line Supervisor will consider such things as compliance history of the establishment, number of plants on the assignment, number of inspectors on the assignment, etc.

When the CSI understands the SPS regulatory requirements and determines which ones he or she will verify, he or she should refer to Table 1. This table references the pages in the Handbook where the CSI can find questions to ask when in verifying that the establishment is meeting each regulatory requirement. These questions will assist the CSI in understanding the thought process he or she should follow in performing the inspection methodology and making regulatory decisions.

If the CSI determines that there is noncompliance with any of the requirements, he or she should refer to pages IV-1 through IV-6 for instructions on documenting the noncompliance. If the noncompliance is part of a trend, the CSI should refer to pages IV-13 through IV-15 for instructions on how and when to link non-compliances. If the CSI decides, based on observations and review of the situation, that issuance of a Notice of Intended Enforcement (NOIE) is necessary, he or she should refer to page IV-14 for instructions.

Page I-30 of Handbook 5000.1, explains the importance of SPS regulatory compliance and the impact that noncompliance can have on other food safety systems. This material is provided particularly for CSOs, although it may be of interest to all FSIS inspection program personnel.

B. How do CSIs and CSOs use the Handbook and tables for the Sanitation Standard Operating Procedure (SOPs) regulations?

When a CSI is to perform one of the Sanitation SOPs procedures (01A01, 01B01, 01B02, 01C01, and 01C02), the CSI should review pages I-21 through I-24, to ensure that he or she understands the correct methodology to use. When performing the Sanitation SOP procedures, the CSI should verify as many of the Sanitation SOP regulatory requirements as possible. The CSI should refer to Table 2 for the specific pages of the Handbook that describe the thought process that he or she should use to verify an establishment's compliance with the Sanitation SOPs regulatory requirements.

If the CSI determines that there is noncompliance with any of the requirements, he or she should refer to pages IV-1 through IV-8 for instructions on documenting the Sanitation SOP noncompliance. If the noncompliance is part of a trend, refer to pages IV-13 through IV-15 for instructions on appropriately linking the noncompliances. If the CSI decides, based on observations and review of the situation, that issuance of an NOIE is necessary, he or she refer to page IV-14. Page IV-20 describes the actions that should be taken when a CSI determines that the establishment shipped adulterated or misbranded product.

Pages I-30 and I-31 of Handbook 5000.1 provide questions that a CSO should ask when assessing the design of the Sanitation SOP. Pages IV-16 and IV-17 provide instructions to the CSOs on documenting their findings during comprehensive food safety assessments.

C. How do CSIs and CSOs use the Handbook and tables for Hazard Analysis and Critical Control Point (HACCP) regulations?

When a CSI is to perform one of the HACCP procedures (03A01, 03B01-03J01, 03B02-03J02), the CSI should review pages II-3 through II-5 to ensure that he or she understands the correct inspection methods to use when performing these procedures. The CSI should refer to Table 3 for the specific pages of the Handbook that describes the HACCP regulatory requirements. These pages describe the thought process that the CSI should use when verifying an establishment's compliance with the HACCP regulatory requirements.

If the CSI determines that there is noncompliance with any of the HACCP requirements, he or she should refer to pages IV-1 through IV-13 for instructions on documenting the HACCP noncompliance. If the noncompliance is part of a trend, refer to pages IV-13 through IV-15 for instructions on appropriately linking the noncompliances. If a CSI determines, based on observations and review of the situation, that issuance of an NOIE is necessary, he or she should refer to page IV-14 for instructions on proceeding with enforcement actions. Page IV-20 describes the actions that should be taken if the CSI determines that the establishment shipped adulterated or misbranded product.

Pages II-31 through II-39 of Handbook 5000.1 provide questions that the CSOs should seek answers to when conducting an assessment of the design of the HACCP systems. Pages IV-16 and IV-17 provide instructions to the CSOs on documenting their findings during the comprehensive food safety assessment.

D. How do CSIs and CSOs use the Handbook and tables the pathogen reduction regulations?

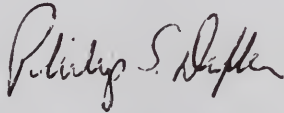
When the CSI is to perform the 05A02 procedure, the CSI should review page III-3 of the Handbook to understand the correct inspection methods to use. The CSI should refer to Table 4 for the specific pages of the handbook that describes the *E. coli* regulatory requirements. These pages describe the thought process the CSI should use when verifying the *E. coli* regulatory requirements.

If the CSI determines there is noncompliance with any of the requirements, he/she should refer to pages IV-1 through IV-13 for instructions on documenting the *E. coli* noncompliance. If the noncompliance is part of a trend, refer to pages IV-13 through IV-15 for instructions on appropriately linking the noncompliances.

If the CSI decides, based on observations and review of the situation, that issuance of an NOIE is necessary, he or she should refer to page IV-14 for instructions on proceeding with enforcement actions.

Pages III-10 and III-11 provide instructions to the CSO on the approach that should be used when conducting an assessment of the *E. coli* written procedures. Pages III-12 through III-15 discuss the role of the CSO as a member of an IDV team for *Salmonella* set failures. Pages IV-16 and IV-17 provide instructions to the CSOs on documenting the results of the comprehensive food safety assessments.

Direct questions to the Technical Service Center.



Deputy Administrator
Office of Policy and Program Development

Attachments





United States
Department of
Agriculture

Food Safety
and Inspection
Service

FSIS Directive
5000.1

Revision 1

Attachment 1

VERIFYING AN ESTABLISHMENT'S FOOD SAFETY SYSTEM HANDBOOK

2010-2011
2011-2012
2012-2013
2013-2014
2014-2015

INTRODUCTION

LIST OF ACRONYMS

TABLES

CHAPTER I SANITATION

CHAPTER II HACCP

CHAPTER III PATHOGEN REDUCTION ACTIVITIES

CHAPTER IV ENFORCEMENT

INTRODUCTION

If FSIS is to effectively perform its role as a public health regulatory agency, it must have a field force that has a good understanding of how to do its job in a way that will help the Agency meet its public health goals. The intent of this document is to provide comprehensive direction to FSIS field personnel on their responsibilities to protect the public health by effecting the pathogen reduction, sanitation, and HACCP regulations. It provides this direction in a number of ways. First, it provides Consumer Safety Inspectors (CSIs) with the steps they will use to perform the activities necessary to verify that a food safety system is operating in compliance with the regulations and in a way that will result in safe food. It also provides Consumer Safety Officers (CSOs) with the methodology that they will use to verify that the systems are properly designed, in accordance with the regulations. Second, it provides CSIs and CSOs with a series of questions that they are to use in developing a thought process that will help them in assessing the establishment's food safety system and in making regulatory compliance determinations. Third, it is designed to assist the various components of the workforce to understand that they each have different, but complementary, responsibilities in verifying that an establishment's food safety system meets regulatory requirements.

The handbook is set out in four chapters. The first chapter addresses Sanitation Performance Standards and Sanitation SOPs. The second chapter addresses HACCP; the third chapter is on generic *E. coli* and *Salmonella* Performance Standard Testing; and the fourth chapter covers documentation and enforcement.

The first three chapters provide CSIs with:

1. a description of the verification activities that they are to perform;
2. the questions that they are to consider in performing those verification activities; and
3. some general examples of noncompliance.

The first three chapters also provide CSOs with the methodology that they are to use in conducting a comprehensive assessment of food safety systems in operation. The CSO conducts a comprehensive assessment of all food safety systems by assessing each individual food safety system in the establishment. If the CSO determines that there are design flaws or execution problems in a system, the CSO will determine whether these flaws or problems have an impact on other food safety systems in the establishment by comparing data from one system to another. The CSO has an understanding that the food safety systems

should interact with each other to provide a sanitary environment for the manufacture of safe food.

The fourth chapter provides CSIs with:

1. instructions for completing an accurate and useful noncompliance record;
2. guidance for determining trends and relationships among noncompliances; and
3. an explanation of the Rules of Practice.

In addition, this chapter provides CSOs with instructions on how to document the findings of the comprehensive assessments of food safety systems that they perform. The CSO does not document a record based on an individual finding but completes documentation based on an assessment of his or her findings about the whole system. This documentation can support a conclusion that the food safety systems in operation meet regulatory requirements, or that the food safety systems in operation do not meet regulatory requirements. If an establishment takes corrective and preventive action in response to a CSO's comprehensive assessment, expressed in the form of a 30-day reassessment letter or an NOIE, the CSO will develop a verification plan for the CSI to use to verify the regulatory requirements are met.

This handbook is also for use by Front-line Supervisors and District Office personnel, in conjunction with the IPPS Supervisory Guidelines, to ensure that CSIs and food inspectors understand their roles in appropriately verifying establishments' food safety systems.

To use this handbook, CSIs and CSOs must understand that to appropriately verify food safety systems, they need to employ critical thinking. Each official establishment has a unique food safety system that should be designed to address that establishment's food processing steps and environment. CSIs and CSOs thus must realize that verification is not a one-size-fits-all exercise. The questions presented in this directive are intended to guide both CSIs and CSOs in an approach that focuses on the specific food safety system with which they are confronted.

The examples provided in this handbook are only examples. When following the instructions, methodology, and guidance in this directive, CSIs and CSOs need to use their professional judgment to make informed and factually supportable decisions.

ACRONYMS USED THROUGHOUT THIS DOCUMENT

Aerobic Plate Counts	APC
Association of Official Analytical Chemists	AOAC
Consumer Safety Inspectors	CSI
Consumer Safety Officers	CSO
Critical Control Point	CCP
District Manager	DM
District Office	DO
Environmental Protection Agency	EPA
Federal Meat Inspection Act	FMIA
Food and Drug Administration	FDA
Food Safety and Inspection Service	FSIS
Hazard Analysis and Critical Control Point	HACCP
In-Depth Verification Review	IDV
Inspection System Procedure	ISP
Inspector-in-Charge	IIC
<i>Listeria monocytogenes</i>	<i>Lm</i>
Most Probable Number	MPN
National Advisory Committee on Microbiological Criteria for Foods	NACMCF
Noncompliance Record	NR
Notice of Intended Enforcement Action	NOIE
Other Consumer Protection	OCP

Pathogen Reduction Enforcement Program	PREP
Performance Based Inspection System	PBIS
Poultry Products Inspection Act	PPIA
Ready-to-Eat	RTE
Sanitation Performance Standards	SPS
Sanitation Standard Operating Procedures	Sanitation SOP
Supervisory Veterinary Medical Officer	SVMO
Technical Service Center	TSC

Table 1. Sanitation Performance Standards

If you are to perform an:	What the CSI does	To do this you should consult one or more of the following for each procedure:	If there is noncompliance, you should consult:
06D01	<p>The CSI should select the SPS requirement or requirements that he or she is going to verify. These requirements are in 9 CFR 416.2 – 416.5.</p> <p>Once the CSI has determined which requirements to verify, he or she will verify regulatory compliance with those requirements by following the instructions on the pages listed for each requirement.</p>	<p>Grounds and Pest Control (416.2(a)), pages I-4–6</p> <p>Construction (416.2(b)), pages I-6–8</p> <p>Lighting (416.2(c)), pages I-8-9</p> <p>Ventilation (416.2(d)), pages I-9-10</p> <p>Plumbing and Sewage (416.2(e)), pages I-10-11</p> <p>Sewage Disposal (416.2(f)), pages I-10-11</p> <p>Water Supply and Water, Ice, and Solution Reuse requirements (416.2(g)), pages I-12-14</p> <p>Dressing Rooms and Lavatories (416.2(h)), pages I-15-16</p> <p>Equipment and Utensils (416.3(a)(b)(c)), pages I-16-17</p> <p>Sanitary Operations (416.4(a)(b)(c)), pages I-17-19</p> <p>Employee Hygiene (416.5(a)(b)(c)), pages I-19-21</p>	<p>If the CSI finds that there is <u>noncompliance</u> with one or more of the regulatory requirements, he or she should refer to pages IV-1-6 for instructions on the completion of a noncompliance record.</p> <p>If the CSI finds that there is a <u>trend of noncompliance</u> occurring, he or she should refer to pages IV-13-15 for instructions on NR linkage.</p> <p>If the CSI finds that an <u>enforcement action</u> should be recommended, he or she should refer to pages IV-18-25 for instructions on the Rules of Practice.</p>

Table 2. Sanitation Standard Operating Procedures

If you are to perform an:	What the CSI does	To do this you should consult:	If there is noncompliance, you should consult:
01A01 01B01 01B02 01C01 01C02	The CSI or food inspector performs one of the verification procedures to determine whether there is regulatory compliance with the implementation, maintenance, corrective action, and recordkeeping requirements of the sanitation SOP regulations.	How to conduct the Sanitation SOP verification procedures, pages I-22-24 AND one of the following sections: Implementation (Monitoring) (416.13), page I-25 Maintenance (416.14), page I-26 Corrective action (416.15), pages I-27-28 Recordkeeping (416.16) pages I-28-29	<p>If the CSI finds that there is <u>noncompliance</u> with one or more of the regulatory requirements, he or she should refer to pages IV-1-3 and IV-6-8 for instructions on the completion of a noncompliance record.</p> <p>If the CSI finds that there is a <u>trend of noncompliance</u> occurring, he or she should refer to pages IV-13-15 for instructions on NR linkage.</p> <p>If the CSI finds that an <u>enforcement action</u> should be recommended, he or she should refer to pages IV-18-25 for instructions on the Rules of Practice.</p>

Table 3. HACCP Verification Procedures

If you are to perform an:	What the CSI does	To do this, you should rely on:	If there is noncompliance , you should rely on:
<p>03A01</p> <p>03B01 – 03J01</p> <p>03B02 – 03J02</p>	<p>The CSI performs one of the verification procedures to determine whether there is regulatory compliance with monitoring, verification, corrective action, recordkeeping, and reassessment requirements</p>	<p>How to conduct the HACCP 01 and 02 procedures, pages II-4-5</p> <p>AND one of the following sections:</p> <p>Verification of hazard analysis, pages II-6-7</p> <p>Verification of monitoring (417.2(c)(4)), pages II-8-9</p> <p>Verification of verification (417.2(c)(7), 417.4(a)(2)(i)(ii)(iii)), pages II-10-12</p> <p>Verification of recordkeeping (417.2(c)(6), 417.5(a)(1), 417.5(a)(2), 417.5(a)(3), 417.5(b), 417.5(c), 417.5(d), 417.5(e)(1)(2)), pages II-13-21</p> <p>Verification of corrective action (417.3(a), 417.3(b)), pages II-22-26</p> <p>Verification of reassessment (417.3(b)(4), 310.25(b)(3)(ii), 381.94(b)(3)(ii), 417.4(a)(3), 417.4(b)), pages II-27-30</p>	<p>If the CSI finds that there is <u>noncompliance</u> with one or more of the regulatory requirements, he or she should refer to pages IV-1-3 and IV-8-12 for instructions on the completion of a noncompliance record.</p> <p>If the CSI finds that there is a trend of <u>noncompliance</u> occurring, he or she should refer to pages IV-13-15 for instructions on NR linkage.</p> <p>If the CSI finds that an <u>enforcement action</u> should be recommended, he or she should refer to pages IV-18-25 for instructions on the Rules of Practice.</p>

Table 4. Pathogen Reduction Verification Procedures

If you are to perform an:	What the CSI does	To do this you should consult:	If there is noncompliance, you should consult:
*05A01 05A02	The CSI performs the verification procedure to determine whether there is regulatory compliance with the <i>E. coli</i> testing requirements.	<p>How to conduct the verification procedure, pages III-3-4</p> <p>AND one of the following sections:</p> <p>Verification of sample collection (310.25(a)(2)(ii), 381.94(a)(2)(ii)), page III-4</p> <p>Verification of sampling frequency (310.25(a)(1)(i), 381.94(a)(1)(i), 310.25(a)(2)(iii), 381.94(a)(2)(iii), 310.25(a)(2)(iv), 381.94(a)(2)(iv), 310.25(a)(2)(v), 381.94(a)(2)(v)), pages III-5-7</p> <p>Verification of sampling analysis (310.25(a)(1)(ii), 381.94(a)(1)(ii), 310.25(a)(3), 381.94(a)(3)), page III-7, Chapter III</p> <p>Verification of recording test results (310.25(a)(1)(iii), 381.94(a)(1)(iii), 310.25(a)(4), 381.94(a)(4)), page III-8</p>	<p>If the CSI finds that there is <u>noncompliance</u> with one or more of the regulatory requirements, he or she should refer to pages IV-1-3 and IV-12-13 for instructions on the completion of a noncompliance record.</p> <p>If the CSI finds that there is a <u>trend of noncompliance</u> occurring, he or she should refer to pages IV-13-15 for instructions on NR linkage.</p> <p>If the CSI finds that an <u>enforcement action</u> should be recommended, he or she should refer to pages IV-18-25 for instructions on the Rules of Practice.</p>

*The frontline supervisor reviewing a plant prior to awarding a grant of inspection would perform the 05A01 procedure.

CHAPTER I TABLE OF CONTENTS

SANITATION

TOPIC	PAGE
Introduction	I-1
Part I Sanitation Performance Standards (SPS)	I-2
CSIs	I-3-29
Part I Verification for SPS	I-3-4
Part II Verification for Grounds and Pest Control	I-4-6
Part III Verification for Construction	I-6-8
Part IV Verification for Lighting	I-8-9
Part V Verification for Ventilation	I-9
Part VI Verification for Plumbing and Sewage	I-10-11
Part VII Verification for Water Supply and Water, Ice and Solution Reuse	I-11-14
Part VIII Verification for Dressing Rooms and Lavatories	I-14-15
Part IX Verification for Equipment and Utensils	I-15-17
Part X Verification for Sanitary Operations	I-18
Part XI Verification for Employee Hygiene	I-18-20
Part XII Sanitation SOPs	I-20
Part XIII Inspection Procedures	I-20-23
01B01 Procedure	I-21
01C01 Procedure	I-21-22
01B02 Procedure	I-22
01C02 Procedure	I-23

Part XIV Verification for Implementation and Monitoring	I-23-24
Part XV Verification for Maintenance	I-24-25
Part XVI Verification for Corrective Actions	I-25-26
Part XVII Verification for Recordkeeping	I-26-27
CSOs	I-28-29
Part I Sanitation Performance Standards	I-28
Part II Sanitation SOPs	I-28-29

CHAPTER I - SANITATION

I. Introduction

The FMIA and PPIA both establish that a meat or poultry product is adulterated if it has “been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.” When FSIS personnel inspect the grounds, facilities, and equipment at meat and poultry establishments, they are looking for these insanitary conditions. To determine whether conditions in or around an establishment are insanitary, inspection program personnel must ask the question posed by the Acts: “Could these conditions cause product to be contaminated with filth or cause product to be unsafe?”

There are so many ways that insanitary conditions can cause product to be adulterated that they cannot all be listed. Instead, this handbook explains the intent of the sanitation regulations and gives examples of some of the ways inspection program personnel can determine whether a meat or poultry establishment is operating under insanitary conditions.

Inspected establishments must meet two sets of regulations concerning sanitation: The Sanitation Standard Operating Procedures (Sanitation SOP) requirements and the Sanitation Performance Standards (SPS). Under the Sanitation SOP requirements, each establishment must develop, implement, and maintain written procedures for the actions it takes daily, before and during operations, to prevent product from being directly contaminated and adulterated. An establishment's Sanitation SOP typically covers the scheduled, daily pre-operational and operational cleaning and sanitation of equipment and surfaces that may contact product directly. The SPS regulations cover all of the other aspects of plant sanitation that can affect food safety, e.g., pest control, adequate ventilation and lighting, and plumbing systems. Keep in mind that these two sets of regulations overlap somewhat in the plant activities they cover. Also, some establishments may address certain sanitation problems within their HACCP plans.

Part XIV Verification for Implementation and Monitoring	I-23-24
Part XV Verification for Maintenance	I-24-25
Part XVI Verification for Corrective Actions	I-25-26
Part XVII Verification for Recordkeeping	I-26-27
CSOs	I-28-29
Part I Sanitation Performance Standards	I-28
Part II Sanitation SOPs	I-28-29

CHAPTER I - SANITATION

I. Introduction

The FMIA and PPIA both establish that a meat or poultry product is adulterated if it has “been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.” When FSIS personnel inspect the grounds, facilities, and equipment at meat and poultry establishments, they are looking for these insanitary conditions. To determine whether conditions in or around an establishment are insanitary, inspection program personnel must ask the question posed by the Acts: “Could these conditions cause product to be contaminated with filth or cause product to be unsafe?”

There are so many ways that insanitary conditions can cause product to be adulterated that they cannot all be listed. Instead, this handbook explains the intent of the sanitation regulations and gives examples of some of the ways inspection program personnel can determine whether a meat or poultry establishment is operating under insanitary conditions.

Inspected establishments must meet two sets of regulations concerning sanitation: The Sanitation Standard Operating Procedures (Sanitation SOP) requirements and the Sanitation Performance Standards (SPS). Under the Sanitation SOP requirements, each establishment must develop, implement, and maintain written procedures for the actions it takes daily, before and during operations, to prevent product from being directly contaminated and adulterated. An establishment’s Sanitation SOP typically covers the scheduled, daily pre-operational and operational cleaning and sanitation of equipment and surfaces that may contact product directly. The SPS regulations cover all of the other aspects of plant sanitation that can affect food safety, e.g., pest control, adequate ventilation and lighting, and plumbing systems. Keep in mind that these two sets of regulations overlap somewhat in the plant activities they cover. Also, some establishments may address certain sanitation problems within their HACCP plans.

PART I -- Sanitation Performance Standards

A. What are the general regulatory requirements for the SPS?

Section 416.1 states: *Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.*

The FSIS regulations in 9 CFR 416.2 to 416.5 set forth more specific performance standards that each official establishment must meet to prevent the creation of insanitary conditions that could cause the adulteration of meat and poultry products. These regulations provide the sanitation standards the establishment must meet for the Federal mark of inspection to be applied to its products. Some of the SPS address conditions within or around the establishment (e.g., ventilation, lighting, facility and equipment construction, and maintenance of the grounds). Other SPS address establishment operations and so may be met by an establishment through its Sanitation SOP (e.g., sanitizing of food contact surfaces) or its HACCP plan (e.g., water reuse).

B. What is the relationship between the SPS and the Sanitation SOPs?

The SPS regulations and the Sanitation SOP regulations are set out in separate sections of 9 CFR part 416. Compliance with both, however, is necessary if an establishment is to prevent the creation of insanitary conditions that can cause the adulteration of product. The SPS regulations define generally what the establishment's sanitation efforts must accomplish to maintain the facilities and environment in a sanitary condition. The Sanitation SOP regulations define specifically what the establishment must accomplish to prevent direct contamination of product. Establishment management may choose to address some of the SPS requirements in their written Sanitation SOP or even within their HACCP plan.

CSIs

PART I – Verification Activities for Sanitation Performance Standards

A. In general, how do CSIs verify the Sanitation Performance Standards?

As scheduled by the PBIS, CSIs verify that establishments are complying with the SPS (9 CFR 416.2 – 416.5) and the Sanitation SOPs (9 CFR 416.11 – 416.16).

CSIs may directly observe conditions in the establishment or review records to verify that the establishment is complying with the sanitation regulatory requirements.

9 CFR 416.4(c) requires that an establishment have “documentation substantiating the safety of a chemical’s use in a food processing environment,” 9 CFR 416.2(g) states: “If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.” The other SPS regulations do not require that an establishment maintain records of the procedures that it uses to meet these performance standards. Establishments may incorporate SPS procedures as part of its Sanitation SOPs, in which case they would have to meet the relevant recordkeeping requirements for Sanitation SOPs.

If an establishment’s procedures, or the prerequisite programs that it uses to meet the SPS, are referenced in the hazard analysis, HACCP plan, or Sanitation SOP, the records associated with the procedures are required to be available to FSIS.

Most of the time the CSIs will verify compliance with the SPS regulatory requirements by directly observing the conditions in the establishment.

The 06D01 procedure is used to verify compliance with the SPS requirements in one or more areas of the establishment. If the CSI determines that the establishment is meeting the sanitation regulatory requirements in a particular area of the establishment, the procedure would be documented on the procedure schedule as performed. The CSI must use professional knowledge and good judgment in making the determination whether the SPS requirements are met. The CSI must assess the situation in the establishment and then determine whether the situation creates insanitary conditions, causes adulteration of product, or prevents FSIS from performing inspection. This means that there can

be conditions in the facility that are less than perfect but that would not represent noncompliance with the SPS regulatory requirements because they are not creating insanitary conditions, adulterating product, or preventing FSIS personnel from performing inspection activities.

If the establishment is not meeting the regulatory requirements, it is the CSI's responsibility to initiate the appropriate regulatory control actions to gain regulatory compliance. The examples used in this section are to demonstrate the decisionmaking process that the CSI might use in making regulatory compliance determinations.

PART II -- Verification of the Grounds and Pest Control

A. What is the regulation related to grounds and pest control?

Section 416.2 (a) states: *The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.*

B. How are CSIs to go about verifying the grounds provision of 416.2(a)?

Establishment situations will dictate the level of verification that must be done. Although an establishment must have a pest management program, it need not be written. If establishment management decides to have a written program, it may or may not be included in the Sanitation SOP. If the establishment has included a written pest management program as part of the Sanitation SOP, the CSI verification activities should include reviewing the Sanitation SOP, reviewing the Sanitation SOP records, and directly observing the procedures being monitored. The CSI should verify that the procedures in the Sanitation SOP are being implemented and monitored, that the establishment is documenting in the Sanitation SOP records the monitoring of the procedures, and that any necessary corrective actions are taken.

Verification is much different if the establishment has no written procedures. Since there are no recordkeeping requirements for grounds and pest control, the CSI will verify that the establishment is meeting the requirements by making observations of the outside grounds and pest control. The CSI will check the outside premises to verify that there are no breeding or harborage areas for pests. The CSI will also verify that there is no harborage or breeding of pests within the establishment by inspecting areas of the establishment for evidence of pests. Noncompliance with this regulatory requirement does not have to involve

evidence of pests. The outside grounds and areas within the establishment should be evaluated to verify that no harborage or breeding area exists. If there are areas outside or inside the establishment that are providing harborage or breeding areas for pests, there is noncompliance with this requirement. When verifying this regulatory requirement, the CSI should seek answers to the following questions:

1. Are all outside areas on the official premises maintained in a manner to prevent harborage and breeding of pests?
2. Are all areas within the establishment maintained in a manner to prevent harborage and breeding of pests?
3. Does the establishment have a pest management program?
4. Does the establishment have a written pest management program as part of the Sanitation SOP?
5. If the pest management program is part of the Sanitation SOP, is the establishment monitoring this program?

C. Example of decisionmaking in judging whether there is compliance with this provision.

CSIs will have to use good judgment in making compliance determinations. The CSI must assess all of the information associated with every observation. For example, the CSI observes tall weeds around the facility. Before making a determination about regulatory compliance, the CSI should determine whether the weeds and grass permit harborage and breeding. If the weeds are scattered and do not permit harborage and breeding, there is not noncompliance. If the weeds are so dense as to permit concealment and breeding, there is noncompliance with these regulations.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

D. How are CSIs to go about verifying the pest control substance provision of 416.2(a)?

The second part of this section of the regulations covers the safety, conditions of use, and the application and storage of pest control substances. The CSI will need to gain information about the safety of any such substances the establishment has on hand, the conditions of use, and how they are stored and applied when verifying compliance with these regulations. Some of the information needed could include answers to the following questions:

1. Does the establishment have documentation on file about the safety of the pest control substances?

2. Does the documentation on file include how the pest control substances are to be used?

3. Are the pest control substances being applied as per the conditions and use?

E. Example of decisionmaking in judging whether there is compliance with this provision.

This provision is very straightforward because of the potential for products being adulterated if pest control substances are misused or are not used according to the documentation on file. Therefore, if the establishment does not have documentation on file that the substances are safe and effective, and on how the substances are to be used, there is noncompliance with this provision. If the establishment is applying the substances differently than the documented uses, there is noncompliance. There is also noncompliance if the establishment is storing these substances in a manner that could result in product adulteration.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART III -- Construction

A. What is the regulation related to construction?


Section 416.2 (b) states:

(1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.

(2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.

(3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.

(4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which



inedible product is processed, handled or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(b), the CSI should assess the construction of the facility in one or more areas. To do this, the CSI needs to seek answers to questions like the following:

1. Are the buildings, including their structures, rooms, and compartments, kept in good repair, and are they of sufficient size to allow for processing, handling, and storage of product?
2. Are the walls, floors, and ceilings cleaned and sanitized as necessary?
3. Are the structures, rooms, and compartments kept in good repair?
4. Are the rooms and compartments of sufficient size to allow for processing, handling, and storage of product?
5. Are the walls, floors, ceilings, doors, windows, and other outside openings constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice?
6. Are edible products and inedible products processed, handled, and stored in a manner that prevents product adulteration and the creation of insanitary conditions? Are they processed, handled, and stored separately? If not, is there an opportunity for cross-contamination?

C. Example of decisionmaking in judging whether there is noncompliance with this provision.

The CSI must realize that it is the establishment's responsibility to maintain the facilities in a manner that will not adulterate product or create insanitary conditions. When the CSI is conducting verification procedure 06D01, he or she may observe situations in the establishment in which compliance is not evident. The CSI must evaluate all the information associated with the observation before making a compliance decision. The CSI must remember that the standard used for this requirement is the SPS regulations. The CSI is to assess the condition observed in light of the regulatory requirement and decide whether regulatory requirements have been met.

For example, the CSI observes an area in the establishment that appears to be of insufficient size to allow for storing of product in a manner that prevents insanitary conditions and consequent product adulteration. The CSO should assess the entire situation. If the establishment is able to maintain this area in a

sanitary condition, the establishment is in compliance with the regulation. If there is not adequate space in the area to permit the area to be maintained in a sanitary manner, there is noncompliance with this provision. For example, if the floors and walls cannot be cleaned regularly because of the overcrowded conditions, there is noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART IV -- Lighting

A. What is the regulation related to lighting?

Section 416.2 (c) states: *Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.*

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(c), the CSI should assess the lighting in the facility in one or more areas. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Are the intensity and quality of lighting adequate for the establishment to determine that the products being processed, handled, stored, or examined are unadulterated, and that sanitary conditions are maintained?
2. Are the intensity and quality of lighting adequate for the establishment to determine that equipment and utensils are appropriately cleaned?
3. Are the intensity and quality of lighting adequate in the hand-washing areas, dressing and locker rooms, and toilets for the establishment to determine that sanitary conditions are maintained?

C. Example of decisionmaking in judging whether there is compliance with this provision.

Since this section of the regulation does not set specific amounts of lighting required, the CSI cannot go to an area of the establishment with a light meter and make a compliance determination. When the CSI is verifying this requirement performing the 06D01 procedure, he or she will have to use good judgment and a sound decisionmaking process to determine compliance. The CSI may observe an area of the establishment that appears to have inadequate lighting. He or she must assess the condition in that area to determine whether

the lighting is adequate for the establishment to ensure that sanitary conditions are maintained, and that product is not adulterated. If this is the case, there is compliance with this provision. If the lighting is not adequate to ensure that sanitary conditions are maintained and that product is not adulterated, there is noncompliance with this provision. For example, if the lighting is not adequate to enable establishment employees to determine whether a substance on product is fecal material, the lighting is inadequate, and there is noncompliance.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART V -- Ventilation

A. What is the regulation on ventilation?

Section 416.2 (d) states: *Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.*

B. How may CSIs go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(d), the CSI should assess the ventilation in the facility in one or more areas. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Is the ventilation adequate to control objectionable odors and vapors that could adulterate product or mask the odor of spoiled or otherwise adulterated product?
2. Is the ventilation adequate to control condensation?

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI observes fog or smoke in the cooked meats cooler. When entering the cooler, it appeared that the ventilation was not adequate to control vapors. The CSI assesses the situation and determines that the establishment has placed 10 trays of warm product in the area. The CSI observes that the vapor in the room dissipates before forming any moisture on the ceiling. In this situation, there is not noncompliance. If the vapor coming from the warm product does form moisture on the ceiling, creating an insanitary condition, there is noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART VI -- Plumbing and Sewage

A. What are the regulations related to plumbing and sewage?

Section 416.2 (e) states: *Plumbing systems must be installed and maintained to:*

- (1) Carry sufficient quantities of water to required locations throughout the establishment;*
- (2) Properly convey sewage and liquid disposable waste from the establishment;*
- (3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;*
- (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor;*
- (5) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing; and*
- (6) Prevent the backup of sewer gases.*

Section 416.2 (f) states: *Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.*

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(e) and (f), the CSI should assess the plumbing in the facility in one or more areas. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Are sufficient quantities of water provided throughout the establishment?
2. Does the plumbing system properly convey sewage and disposable waste from the establishment?
3. Does the plumbing system provide adequate floor drainage?

4. Is the plumbing installed to prevent back-flow conditions and cross-connections between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing?

5. Is the plumbing installed to prevent the backup of sewer gases?

6. Is the sewage disposed into a sewage system separate from all other drainage lines or other means to prevent backup of sewage into areas where product is processed, handled, or stored?

7. If the sewage disposal system is a private system requiring approval by a State or local health authority, is the letter of approval available to FSIS upon request?

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI is in the area of the plant where several water-cooking units are being drained simultaneously. There is a gutter drain that the water is drained into, and the end of a cleanup hose is submerged in the gutter drain. The CSI thinks there is noncompliance with this provision but decides to evaluate the situation further. The CSI finds a vacuum breaker at the cleanup station to prevent back siphonage. The CSI determines there is not noncompliance. If there had been nothing to prevent back siphonage, there would be noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART VII -- Water Supply and Water, Ice, and Solution Reuse

A. What is the regulation related to water supply?

Section 416.2 (g) states: *(1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.*

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(g), the CSI should check the water in the facility in one or more areas.

While in these areas, the CSI needs to seek answers to questions like the following:

1. Does the establishment have documentation that the water in the establishment complies with the EPA's National Primary Drinking Water Regulations?
2. Is there adequate water pressure, at a suitable temperature, in all areas where required, for example, for processing product; for cleaning rooms and equipment, utensils, and packaging materials; for employee sanitary facilities?
3. If the establishment uses a municipal water supply, does it have a water report issued under the authority of the State or local health agency certifying or attesting to the potability of the water supply?
4. If the establishment uses a private well for its water supply, does the establishment have on file documentation certifying the potability of the water supply that is renewed semi-annually?

C. What is the regulation related to reuse of water, ice, and solutions for RTE product?

Section 416.2(g)(2) states: *Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.*

D. How are CSIs to go about verifying this regulation?

The CSI should determine whether the establishment is reusing water, ice, or solutions (such as brine, liquid smoke, or propylene glycol) to chill or cook RTE product.

If the establishment is reusing water, ice, or solutions to cook or chill RTE products, the CSI needs to seek answers to these type of questions:

1. Are water, ice, and solutions that are reused maintained free of pathogenic organisms and fecal coliform organisms?

2. Is other physical, chemical, and microbiological contamination reduced to prevent adulteration of product?

3. Did the establishment consider water, ice, and solution reuse in the hazard analysis?

4. If the establishment considered water, ice, and solution reuse in the hazard analysis and found a food safety hazard reasonably likely to occur, is there a CCP in the HACCP plan to address this hazard?

E. What is the regulation related to reuse of water, ice, and solutions for raw product?

Section 416.2(g) states: *(3) Water, ice, and solutions to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on ready-to-eat product.*

(4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section.

(5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.

(6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.

F. How are CSIs to go about verifying this regulation?

CSIs should review sections of the establishment's Sanitation SOP or HACCP plan that address water supply and water, ice, and solution reuse before considering the actual establishment condition. They should assess program

effectiveness pertaining to water supply and water, ice, and solution reuse through observing actual establishment conditions and considering the following:

1. Is the potable water supply from a municipal source? If not, does the certification or other documentation on file evidence that the establishment's potable water supply meets the EPA's primary potability requirements for sources of drinking water?

2. Is there an adequate supply of potable water in the establishment?

3. Are the ice-making equipment, rooms, and augers maintained in good repair and sanitary condition?

4. Is water, ice, and solutions reuse accomplished properly and according to 9 CFR 416.2?

NOTE: The regulations state that water may be reused "for the same purpose." This means that water used to wash or otherwise process raw product may be reused to wash or otherwise process raw product, even at a different point in processing, provided that "measures are taken to reduce physical, chemical, or microbiological contamination." For example, an establishment could reuse poultry chiller water in a scalding tank. Furthermore, water used to process RTE product could be reused to wash or process raw product. But water used to process raw product may not be reused to process RTE product. For example, an establishment could not reuse poultry chiller water for cooking or cooling packaged RTE product.

PART VIII -- Dressing Rooms and Lavatories

A. What is the regulation related to dressing rooms and lavatories?

Section 416.2 (h) states: *(1) Dressing rooms, toilet rooms and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.*

(2) Lavatories with running hot and cold water, soap, and towels must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.

(3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(h), the CSI should assess the dressing rooms, toilet rooms, and urinal rooms. The CSI should also assess the lavatories in one or more areas of the establishment. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Are the dressing rooms, toilet rooms, and urinals sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair?
2. Are dressing rooms, toilet rooms, and urinals separate from the rooms and compartments in which products are processed, stored, or handled?
3. Are there lavatories with running hot and cold water, soap, and towels placed in or near toilet and urinal rooms and other places in the establishment as necessary?
4. Are refuse receptacles constructed and maintained in a sanitary manner?

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI is in an area of the establishment where edible product is being handled. There are several employees working in this rather large room. The CSI observes that there is only one lavatory close by. The CSI thinks that there may be noncompliance with this requirement but decides to evaluate the situation further before making a compliance determination. The CSI observes that the employees are handling product, and when employees' hands are contaminated, they go to the lavatory and wash their hands. The CSI determines that in this situation, there is not noncompliance. If the employees were not washing their hands because the lavatory was not appropriately located in this area, there would be noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART IX -- Equipment and Utensils

A. What is the regulation related to equipment and utensils?

Section 416.3 states: *(a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage.*

Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.

(b) Equipment or utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.

(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.3, the CSI should assess the equipment and utensils in one or more areas of the establishment. While in these areas, the CSI should also verify that the receptacles used for storing inedible material meet the regulatory requirements. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Are the equipment and utensils used for processing and otherwise handling edible product or ingredients of material and construction that facilitates thorough cleaning?
2. Are equipment or utensils constructed, located, or operated in a manner that prevents inspection program personnel from inspecting the sanitary condition of the equipment or utensils?
3. Are receptacles used for storing inedible material constructed of materials that can be maintained in a sanitary manner?
4. Are receptacles used for storing inedible products marked conspicuously and distinctively to identify permitted uses?

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI observes a closed system that had not been disassembled for cleaning. The CSI does not believe that there is noncompliance with this provision but decides to assess the situation further before making a compliance determination. By looking into the matter, he or she determines that this system is cleaned-in-place, and that there are inspection openings at every change of direction to allow for verification of the effectiveness of the sanitation procedures. The CSI inspects the system through the openings and finds that the closed

system is being adequately cleaned. There is compliance with this provision. If the closed system did not permit inspection or was creating insanitary conditions, there would be noncompliance with this provision. The CSI should keep in mind that the establishment may choose to meet the requirements of 9 CFR 416.3 through its Sanitation SOP or through other activities it conducts to comply with the SPS regulations.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART X -- Sanitary Operations

A. What is the regulation related to sanitary operations?

Section 416.4 states: *(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.*

(b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food-processing environment must be available to FSIS inspection program employees for review. [In most cases the documentation will be "Material Safety Data Sheets."]

(d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.4, the CSI should assess how the equipment and utensils in one or more areas of the establishment are cleaned and handled. The CSI should assess whether products are protected from adulteration during processing, handling, storage, loading, and unloading, and during transportation. The CSI should also assess use, handling, and storage of cleaning compounds, sanitizing agents, processing aids, and other chemicals in the establishment. The CSI needs to seek answers to questions like the following:

1. Are all food-contact surfaces of facilities, equipment, and utensils cleaned and sanitized as frequently as necessary to prevent insanitary conditions and the adulteration of product?

NOTE: Many establishments will comply with the requirements of Section 416.4(a) through Sanitation SOP activities.

2. Are non-food contact surfaces of facilities, equipment, and utensils used in the operation of the establishment cleaned and sanitized as necessary to prevent the creation of insanitary conditions and the adulteration of product?

3. Are the cleaning compounds, sanitizing agents, processing aids, and other chemicals used by the establishment safe and effective under the conditions of use?

4. Does the establishment have documentation substantiating the safety of a chemical's use in a food processing environment?

5. Does the establishment protect product from adulteration during processing, handling, storage, loading and unloading, and transportation from official establishments?

6. If the establishment uses extended clean-up procedures, are these procedures included in the Sanitation SOP?

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI observes several vats of meat in the raw product storage area that are not covered. There are several other vats of meat stored in this area that are covered. The CSI thinks that there might be noncompliance with this provision but decides to evaluate the situation further before making a compliance determination. The CSI looks at the overhead in the area and does not observe any conditions that would constitute insanitation or that would cause product adulteration. The CSI observes an employee come into the area and take a vat of product out of this area. The CSI follows the employee to determine whether the product needs to be protected while being transferred to another area. The CSI finds no conditions that would require the product to be covered during transit. Therefore, the CSI determines that there is not noncompliance with this provision. If the CSI had observed that there was a condition in the establishment that could adulterate product during storage or handling, there would be noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART XI -- Employee Hygiene

A. What is the regulation related to employee hygiene?

Section 416.5 states: *(a) Cleanliness. All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.*

(b) Clothing. Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.

(c) Disease control. Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.5, the CSI should assess employee hygiene in one or more areas of the establishment. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Are the persons in contact with product, food-contact surfaces, and product-packaging materials adhering to hygienic practices?
2. Are aprons, frocks, and other outer clothing worn by persons who handle product made of material that is disposable or readily cleaned?
3. Are clean garments worn at the start of the day and changed during the day as often as necessary?
4. Are persons who appear to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination excluded from any operations that could result in product adulteration and the creation of insanitary conditions?

NOTE: The regulations pertaining to employee hygiene also apply to FSIS personnel. As representatives of a public health agency, it is imperative that inspection program personnel lead through example and follow all provisions in 9

CFR 416.3 and 416.5 during the performance of their official duties within federally inspected meat and poultry product establishments. Inspection program personnel must adhere to establishments' special requirements as well. In this manner, FSIS can aid in maintaining the sanitary conditions inside the facilities to which FSIS personnel are assigned. These regulations do not require establishment employees to wear frocks or smocks, but require outer clothing to be of material that is disposable or readily cleanable. If inspection program personnel have questions about an employee having an infectious disease, he or she should discuss this with plant management. Inspection program personnel are not trained to diagnose infectious diseases. If the establishment has requirements that are more stringent than the SPS requirements, inspection program personnel are expected to follow those requirements.

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI observes an employee preparing to start to work in the raw product area. The employee puts on an apron. The CSI observes that the apron is dirty from the previous day's production. The CSI thinks that there is noncompliance with this provision but decides to evaluate this situation further before making a compliance determination. He observes the employee go to the washroom and clean the apron thoroughly before starting to work. The CSI determines that there is not noncompliance with this provision. If the employee does not clean the apron appropriately before going to work, there would be noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART XII -- Sanitation SOPs

A. What are the written Sanitation SOP Procedures?

The establishment has the responsibility to develop, implement, and maintain written Sanitation SOPs. The basic regulatory requirements are described in 9 CFR 416.12. At the time inspection is granted, the establishment must have a Sanitation SOP that meets these requirements. The CSI performs the 01A01 procedure to verify that the written procedures meet the basic regulatory requirements. The CSI determines when it is necessary to perform the 01A01 procedure. There are four Sanitation SOP regulatory requirements. The four requirements are: implementation and monitoring, maintenance, recordkeeping, and corrective action. If the CSI determines that the Sanitation SOP does not meet the regulatory requirements specified in 9 CFR 416.12, he or she should contact the DO for direction. The DO will provide direction as to whether the CSI should issue a 30-day reassessment letter, or whether the DO will institute an enforcement action specified in the Rules of Practice, 9 CFR part 500.

PART XIII -- Inspection Procedures

A. What are the inspection procedures for the Sanitation SOPs?

There are two Sanitation SOP procedures for pre-operational sanitation verification (01B01/01B02) and two Sanitation SOP procedures for operational sanitation verification (01C01/01C02). The CSI performs these procedures to verify that the establishment is meeting the Sanitation SOP regulatory requirements. Those requirements are:

1. Implementation and monitoring of Sanitation SOP (416.13);
2. Maintenance of Sanitation SOP (ensuring its effectiveness) (416.14);
3. Sanitation SOP corrective actions (416.15); and
4. Sanitation SOP recordkeeping (416.16)

B. How do CSIs conduct the 01B01 procedures?

The 01B01 Sanitation SOP procedure is the pre-operational recordkeeping procedure. This recordkeeping procedure instructs the CSI to verify the daily documentation of the establishment's implementation and monitoring of the Sanitation SOP procedures and required corrective actions.

When the CSI performs the 01B01 procedure, he or she should review the Sanitation SOP and the establishment's pre-operational Sanitation SOP records to verify that the establishment is meeting the regulatory requirements for pre-operational sanitation.

The CSI should review the Sanitation SOP to become knowledgeable about the procedures in it. The CSI should review the daily pre-operational Sanitation SOP records to verify that the establishment is following the pre-operational procedures, that the monitoring activities are conducted at the specified frequency, that the corrective action requirements are met, and that records are being authenticated by the establishment employee responsible for implementation and monitoring of the Sanitation SOP. This is a recordkeeping procedure and the CSI should be reviewing pre-operational records only to determine if the establishment is meeting the regulatory requirements.

C. How do CSIs conduct the 01C01 procedures?

When the CSI performs the 01C01 procedure, he or she should review the establishment's operational sanitation records to verify that the regulatory requirements for operational sanitation are met.

The CSI should review the Sanitation SOP to become knowledgeable with the procedures in it. The CSI should review the Sanitation SOP operational records to verify that the establishment is following the operational procedures in the Sanitation SOP, that the monitoring activities are conducted at the specified frequency, that the corrective action requirements are met, and that records are being authenticated by the establishment employee responsible for implementation and monitoring of the Sanitation SOP.

D. What are CSIs to do when performing the 01B02 procedure?

The 01B02 Sanitation SOP procedure is a review and observation procedure for verifying pre-operational sanitation. When performing the review and observation procedure, the CSI will verify all four requirements: implementation and monitoring, maintenance, corrective actions, and recordkeeping.

The CSI should review the Sanitation SOP to ensure that he or she is knowledgeable about the current written procedures.

NOTE: The CSI needs to understand the procedures in the Sanitation SOP that the establishment is implementing to prevent direct contamination or other adulteration of product. The CSI should become familiar with any monitoring procedures and frequencies that may be included in the Sanitation SOP. Without this knowledge the CSI will not be able to verify regulatory compliance.

If the CSI is to perform the 01B02 procedure and has reviewed the Sanitation SOP, he or she should verify the pre-operational sanitation requirements by inspecting direct contact surfaces in one or more areas of the establishment, observing the establishment perform the monitoring procedures, and comparing his or her findings with what the establishment has documented.

NOTE: When the CSI is performing the 01B02 procedure, he or she should inspect direct contact surfaces and observe the establishment conduct its monitoring procedures when possible.

4. It is possible that the CSI might be performing his or her review and observation procedure at the same time the establishment is monitoring their pre-operational procedures. This provides an excellent opportunity for the CSI to perform the observation part of this procedure. In some cases, the establishment might conduct its monitoring of the implementation of the Sanitation SOP procedures before inspection program personnel arrive at the establishment. In these situations, the CSI should seek direction from supervisory personnel as to how frequently he or she should directly observe the establishment conduct monitoring.

NOTE: The supervisor should consider several factors when making this decision: 1) establishment compliance history, 2) documentation in the FSIS file, and 3) information from Sanitation SOP records.

E. What are CSIs to do when performing the 01C02 procedures?

The CSI should perform the 01C02 procedure the same way as he or she conducts the 01B02, except this procedure is conducted during operations. Again, the CSI should review the Sanitation SOP to become familiar with all the procedures in the Sanitation SOP.

The CSI should verify that the establishment is meeting the Sanitation SOP regulatory requirements for operational sanitation by:

1. inspecting one or more areas of the establishment to ensure procedures are effective in preventing direct contamination or other adulteration of product,
2. observing the establishment perform the monitoring procedures, and
3. comparing the findings to what the establishment has documented.

It might be difficult for the CSI to observe the establishment conducting its monitoring because 9 CFR 416.13 requires that the establishment monitor the procedures in the Sanitation SOP daily. The CSI might not be available to observe that activity when it is occurring.

PART XIV – Implementation and Monitoring

A. What is the implementation and monitoring regulation?

Section 416.13 states: *Each official establishment shall conduct the pre-operational procedures in the Sanitation SOPs before the start of operations.*

- (a) *Each official establishment shall conduct all other procedures in the Sanitation SOPs at the frequencies specified.*
- (b) *Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOPs.*

B. What are some questions the CSI should consider when performing verification activities for this regulation?

When verifying compliance with 9 CFR 416.13, the CSI should seek answers to the following type of questions:

1. Is the establishment implementing the pre-operational procedures in the Sanitation SOP prior to the start of operations?
2. Are direct contamination or adulteration of product or unclean direct product contact surfaces observed by FSIS or the establishment?

3. Is the establishment conducting the procedures in the Sanitation SOP as specified?

4. Does the Sanitation SOP contain monitoring frequencies?

5. If the Sanitation SOP does not contain monitoring frequencies, is the establishment monitoring the implementation of the procedures in the Sanitation SOP daily?

NOTE: If environmental sampling is included in the Sanitation SOP, the CSI should verify that the establishment is following those procedures. The CSI should observe the establishment collecting samples, should review sample results, and verify that the corrective actions specified in the Sanitation SOP for results that do not meet the criteria of the procedures are taken when necessary. This verification should be completed as part of the Sanitation SOP verification procedures.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART XV -- Maintenance

A. What is the maintenance regulation?

Section 416.14 states: *Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOPs and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.*

B. What are some questions the CSI should consider when performing verification activities for this regulation?

When verifying compliance with 9 CFR 416.14, the CSI will seek answers to questions of the following type:

1. Has the establishment routinely evaluated the effectiveness of the Sanitation SOPs in preventing direct contamination or adulteration of product? Is the establishment doing environmental testing or taking other steps to assess whether its Sanitation SOPs are effective?

2. If changes were made in facilities, equipment, utensils, operations, or personnel, have the Sanitation SOPs been revised to keep them effective?

NOTE: Construction and removal of walls, ceilings, and floors may cause harborage sites for *L. monocytogenes* to be dislodged from otherwise protected areas. The CSI should ask whether the establishment has stepped up its on-

going verification activity to ensure that the current Sanitation SOP or other procedures are adequate to find insanitary conditions.

3. Does the establishment routinely review the Sanitation SOP records to determine if there are trends occurring showing the Sanitation SOP needs revising?

C. What is an example of noncompliance?

- Changes were made in the facilities, equipment utensils, operations, or personnel, and the Sanitation SOP is no longer effective in preventing direct contamination or adulteration of product.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART XVI – Corrective Actions

A. What is the regulation on corrective actions?

Section 416.15 states: (a) *Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOPs or the procedures specified therein, or the implementation or maintenance of the Sanitation SOPs, may have failed to prevent direct contamination or adulteration of product(s).*

(b) *Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOPs and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOPs or the procedures specified therein.*

B. What are some questions the CSI should consider when performing verification activities for this regulation?

When verifying compliance with 9 CFR 416.15, the CSI should seek answers to the following:

1. If there is direct contamination or other adulteration of product, does the establishment implement corrective actions that restore sanitary conditions, prevent recurrence, and make appropriate disposition decisions regarding any product that may be contaminated?

2. Do the corrective actions include the reevaluation and modification of the Sanitation SOPs or improvements in the execution of the procedures when necessary?

NOTE: If the establishment is monitoring the pre-operational sanitation procedures, finding noncompliance, taking the corrective actions required in 9 CFR 416.15, and the CSI is not finding direct contact surfaces that may cause adulterated or contaminated product, the CSI should focus on whether the overall implementation of the Sanitation SOP is effective in preventing direct contamination or other adulteration of product. The CSI should not focus on the fact that the preventive measures being used are the same as previous preventive measures used by the establishment. When the CSI finds direct contact surfaces unclean or direct contamination or adulteration of product, he or she should take a regulatory control action. That regulatory control action should not be relinquished until the establishment has proposed an acceptable preventive measure. There is no noncompliance if the establishment finds such conditions and takes the appropriate corrective actions. These corrective actions include restoring sanitary conditions, making appropriate disposition of product, and implementing measures to prevent recurrence. This thought process would not pertain to situations in which product became contaminated. Since the Sanitation SOP must contain procedures to prevent direct contamination or adulteration of product, FSIS would expect the establishment to have procedures in place to prevent the contamination of product.

C. What are some examples of noncompliance?

- The Sanitation SOP failed to prevent direct contamination or other adulteration of product, and the establishment did not implement corrective actions to ensure appropriate disposition of product.
- The Sanitation SOP failed to prevent direct contamination or other adulteration of product, and the establishment did not implement corrective actions to restore sanitary conditions.
- The Sanitation SOP failed to prevent direct contamination or other adulteration of product, and the establishment did not implement corrective actions to prevent recurrence of direct contamination or adulteration of product. This may lead to a trend of repeated noncompliances.

CSIs will document noncompliance in a manner that accords with Chapter IV of this document.

PART XVII -- Recordkeeping

A. What is the regulation on recordkeeping?

Section 416.16 states: (a) *Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs*

and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOPs as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOPs shall authenticate these records with his or her initials and the date.

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made accessible available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

B. What are some questions the CSI should consider when performing verification activities for this regulation?

When verifying compliance with 9 CFR 416.16, the CSI should seek answers to the following type of questions:

1. Is the establishment maintaining daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken?
2. Is an establishment employee responsible for the implementation and monitoring of the procedures in the Sanitation SOPs and authenticating the records with his or her initials and date?
3. If records are being maintained on computers, are there controls to ensure the integrity of the electronic data?
4. Are Sanitation SOP records being maintained for at least 6 months and available to FSIS?
5. Are Sanitation SOP records kept off-site 48 hours after completion? If so, are they available to FSIS within 24 hours of request?
6. Do the Sanitation SOP records accurately reflect the sanitary conditions of the establishment?
7. Are the Sanitation SOP records available for FSIS at the start of the same shift the following day?

CSIs will document noncompliance in a manner that accords with Chapter IV of this document.

CSOs

PART I -- Sanitation Performance Standards

There are no written procedures required for meeting the SPS, therefore CSOs do not focus on these regulatory requirements directly. For example, if an establishment is consistently failing the *Salmonella* performance standards, the CSO might be asked to conduct an assessment of the establishment's food safety systems, including whether the establishment is complying with the SPS. In performing this assessment, the CSO should be aware of any problems in complying with the SPS that could be having an impact on food safety. For example, if the CSO found that the employee hygiene and product handling practices were not meeting the regulatory requirements, this failure could be having a direct impact on an establishment's ability to meet the *Salmonella* performance standards. The CSO will document all findings in the Comprehensive Assessment of the Execution and Design of an Establishment's Food Safety Systems, described in Chapter IV of this document.

PART II -- Review of Sanitation SOPs

A. What are the CSO responsibilities?

The CSO systemically looks at the Sanitation SOPs. The CSO will focus on the design of the Sanitation SOPs. The CSO should review the Sanitation SOP and at least 60 days' pre-operational and operational sanitation records and try to answer questions similar to the following:

1. Are the Sanitation SOPs designed to include all procedures necessary to prevent direct contamination or adulteration of product?
2. If the establishment is doing microbiological testing as part of the Sanitation SOP, is the design of the procedure appropriate for the organism?
3. If the establishment has an extended cleanup written in the Sanitation SOP, does the design of the procedure support extended cleanup?
4. If the establishment does microbiological testing to verify the extended cleanup procedure, are the testing procedures designed to find the organisms of concern?
5. If the establishment produces RTE products, are the Sanitation SOPs designed in a manner to prevent cross-contamination from raw to RTE products?
6. If the establishment produces RTE products and includes environmental testing in the Sanitation SOPs, are the procedures designed to

increase testing when significant construction occurs?

7. If there is construction going on in the establishment, have the Sanitation SOPs been designed to identify problems that may emerge as a result of the construction, (sanitary conditions, product contamination)?

8. If environmental testing is included as part of the Sanitation SOPs, are the corrective actions designed to meet the corrective action requirements of section 416.15?

9. If the establishment produces RTE products, are the Sanitation SOPs designed to prevent post lethality contamination from personal hygiene, product handling practices, equipment maintenance, etc.?

B. What do CSOs do after the assessment?

When the assessment of the Sanitation SOPs and a minimum of 60 days of associated records is complete, the CSO is to document a supportable Agency position.

CHAPTER II TABLE OF CONTENTS HACCP

Topic	Page
Introduction	II-1-2
CSIs	II-3-27
Part I Verification Methodology	II-3-4
HACCP 01 Procedure	II-4
HACCP 02 Procedure	II-4
Part II Verification of Hazard Analysis	II-5-6
Part III Verification of Monitoring	II-6-8
Part IV Verification of Verification	II-8-10
Part V Verification of Recordkeeping	II-10-19
Part VI Verification of Corrective Actions	II-19-24
Part VII Reassessment Requirement	II-24-27
CSOs	II-28-36
Part I HACCP Assessment	II-28
Part II Review of Hazard Analysis	II-28-31
Part III Assessment of Monitoring	II-31-32
Part IV Assessment of Verification	II-32-33
Part V Assessment of Recordkeeping	II-33-34
Part VI Assessment of Corrective Actions	II-34
Part VII Reassessment	II-34-36

CHAPTER II - HACCP

I. Introduction

The establishment has the responsibility for complying with 9 CFR Part 417 of FSIS HACCP regulations. 9 CFR 417.2(b) requires that every official establishment develop and implement a HACCP plan covering each product produced by that establishment when the establishment's hazard analysis reveals that one or more food safety hazards are reasonably likely to occur in the process of producing the product.

FSIS has the responsibility for verifying that establishments meet the requirements in 9 CFR Part 417. 9 CFR 417.8 describes the FSIS verification functions that are performed to provide a basis for making determinations as to whether the establishment is in compliance.

CSIs focus on the execution or implementation of the HACCP plan when performing their verification procedures. The CSOs focus more on the design of the HACCP plans when they are conducting an assessment of the HACCP system. The purpose of this section is to set out how each component verifies that establishments are complying with Part 417.

In assessing the adequacy of an establishment's HACCP system, inspection program personnel should consider all of the available evidence.

Inspection program personnel should evaluate their observations and the results of the microbiological sampling that they do in an integrated way. Has the inspector observed a laxness in the establishment's attention to evisceration and its application of its antimicrobial interventions that is reflected in a higher number of positives in the Agency's *Salmonella* sampling? Has the inspector observed a commitment to food safety that produces good results?

Moreover, establishments may do their own environmental testing, testing for APCs or enterobacteriaceae, or other verification testing. Inspection program personnel should ask establishment management whether it does its own testing, and whether it would share the test results. The inspector should make clear that it is in the establishment's interest to be doing and sharing such testing.

For example, an establishment that makes RTE product decides to undertake some in-plant construction. Because construction increases the risk of *L. monocytogenes* contamination of product, the establishment decides to treat this pathogen as a hazard that is reasonably likely to occur, at least during the construction period. Inspection program personnel should seek answers to questions similar to the following to determine whether the establishment's HACCP system is producing safe product.

1. What preventive measures were put in place during the construction to prevent product or product contact surface contamination?

2. Is the plant doing environmental testing during the construction project? If so, do the results indicate any significant micro flora changes during the construction project?

3. Did the establishment implement any additional sanitation procedures during the construction project?

4. Did the establishment do any testing to determine the effectiveness of the special sanitation procedures?

If inspection program personnel determine that product samples should be taken during this period, they should contact the Front-line Supervisor. If the plant is doing such testing and makes the results available to inspection program personnel, it may not be necessary for FSIS to intensify its testing. Inspection program personnel should analyze the results of any testing that has been done for evidence of an emerging problem with *L. monocytogenes* or with an indicator organism that would suggest an emerging *L. monocytogenes* problem. If the establishment is conducting environmental testing and is not willing to share the results, the CSI should contact the Front-line Supervisor.

Each situation is different, and inspection program personnel must use critical thinking in deciding whether there is a basis for concern, or that there is a problem with the establishment's HACCP system that should be addressed. If the establishment is not complying with the regulatory requirements, inspection program personnel should issue an NR or consider recommending other action under the Rules of Practice, 9 CFR part 500 (see Chapter IV).

CSIs

PART I -- HACCP Verification Methodology

A. How do CSIs perform HACCP verification procedures?

The CSI should understand the regulations in 9 CFR part 417, how to apply these regulations in the plant environment, and the appropriate methodology to use in verifying compliance with these regulations. There are two HACCP procedures, an 01 procedure and an 02 procedure, for verifying that an establishment is meeting the regulatory requirements of 9 CFR Part 417. The number of HACCP plans and the number of products produced within a specific processing category has no impact on the number of HACCP procedures that CSIs are scheduled to perform for that process.

NOTE: An establishment can produce many products within the same processing category with one HACCP plan, or can have a separate HACCP plan for each product within that processing category. In either case, there are only two HACCP procedures for that processing category. If the establishment has a separate HACCP plan for each of the products in the same processing category, the CSI needs to have a method of verifying that the regulatory requirements are met in all of the HACCP plans at some frequency. He or she might verify one of the five requirements (monitoring, verification, corrective action, recordkeeping, and reassessment) in all of the HACCP plans for a particular processing category each time the HACCP 01 procedure is performed. Another method he or she might use is to choose a different HACCP plan each time that procedure is to be performed.

There are two components to each of the HACCP procedures, a recordkeeping component and a review and observation component. The CSI can use either of these components or a combination of these components to verify regulatory compliance.

1. The CSI might review the establishment records to verify compliance (recordkeeping).
2. Alternatively or in addition, he or she might take measurements and compare the result with the company records to determine regulatory compliance (review). He or she might also observe an establishment employee perform the activity listed in the HACCP plan to verify regulatory compliance (observation).

The CSI may use any of these components or parts, individually or collectively, to verify regulatory compliance with the HACCP regulations. For example, the CSI can review records at one CCP and take a measurement or observe the establishment take a measurement at another CCP to verify that the monitoring requirement is met.

If the CSI questions the contents of the HACCP plan, he or she should review the hazard analysis and the decisionmaking documents supporting the hazard analysis to verify that the establishment can support the contents of the HACCP plan.

HACCP 01 Procedure

The purpose of the HACCP 01 procedure is to determine if the establishment meets the five regulatory requirements. When the HACCP 01 procedure is scheduled it is used for reviewing a random sample of the HACCP regulatory requirements in operation.

NOTE: The CSI must have a method for randomly selecting the requirements that he or she will verify during the performance of this procedure. After this decision is made, the CSI will need to review the HACCP plan to ensure that he or she has full knowledge of what it contains.

HACCP 02 Procedure

The purpose of the HACCP 02 procedure is to determine if the establishment meets the five regulatory requirements. When the HACCP 02 procedure is scheduled it is used to verify that the establishment is following the HACCP plan, establishment personnel are performing the tasks specified in the HACCP plan, corrective actions are taken, and pre-shipment review prevents the shipment of adulterated product for specific production.

NOTE: The CSI can review records, conduct a measurement, and observe the establishment conducting the activities listed in the HACCP plan. However, the CSI must verify that all the applicable requirements at all of the CCPs have been met for a specific production when performing the HACCP 02 procedure. The CSI can verify corrective actions if there has been a deviation from a critical limit, a deviation not covered by a specified corrective action, or an unforeseen hazard.

When the CSI determines that the establishment does not meet one or more of the regulatory requirements, he or she should document this finding on an NR. If the noncompliance involves the production and shipment of unsafe food, the CSI should initiate the appropriate enforcement actions described in 9 CFR 500.3. He or she should ask the DO to issue an NOIE to the establishment. If the CSI has documented multiple or recurring noncompliances, he or she should contact the DO and request that an NOIE be issued to the establishment as described in 9 CFR 500.4. In other situations the CSI may take a regulatory control action to prevent the shipment of adulterated products. The CSI should also keep the Front-line Supervisor informed of developing trends of noncompliance. (see Chapter IV).

PART II -- Hazard Analysis

A. How do CSIs verify that an establishment has performed a hazard analysis?

During the performance of the 03A01 procedure, CSIs verify that an establishment has performed a hazard analysis as part of its basic compliance with the regulations (9 CFR 417.2(a)). The CSIs should use the thought process and methodology described below when verifying that the hazard analysis complies with the regulation. CSIs will verify compliance by reviewing the flow chart, the hazard analysis, the HACCP plan, the establishment's initial validation of the HACCP plan, and HACCP records.

Before reviewing the hazard analysis, the CSIs should understand that a food safety hazard is defined in 9 CFR 417.1 as *any biological, chemical, or physical property that **may** cause a food to be unsafe for human consumption*. The CSIs must review hazard analysis records to determine whether the analysis considered those properties that have a real chance of occurring in the food or in the processing of the food, and of causing the food to be unsafe. The hazard must be one that would be identified by a reasonable consideration of the food, how it is processed, and where safety issues can arise. The fact that it is possible to imagine a hazard (e.g., a meteor may fall onto the plant) does not mean that the hazard analysis must address that hazard. If the CSI has concerns about whether the relevant hazards have been considered, he or she may decide to discuss issues with the TSC or with the establishment during the weekly meeting. The CSI should ask whether the establishment has considered and addressed the following questions by comparing the hazard analysis to the Basic Compliance Checklist (FSIS Form 5000-1):

1. Did the establishment conduct a hazard analysis or have one conducted for it?
2. Did the establishment's analysis start by identifying all hazards that may occur?
3. Does the hazard analysis identify preventive measures the establishment can apply to the food safety hazards?
4. Does the hazard analysis include a flow chart that describes (diagrams) the steps of each process and production flow in the establishment?
5. Does the hazard analysis identify the intended use or the consumers of the finished product?
6. Does the result of the establishment's hazard analysis reveal that one or more food safety hazards are reasonably likely to occur?

7. Does the establishment have a written HACCP plan for each of its products?

8. Has the establishment conducted validation activities to determine whether the HACCP plan will function as intended?

NOTE: Section 417.4 (a)(1) provides more details about the requirement for initial validation, "... The establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan." Validation data for any HACCP plan must include some practical data or information reflecting an establishment's actual experience in implementing the HACCP plan. This is necessary because validation must demonstrate not only that the HACCP plan is theoretically sound, but also that the establishment can implement it and make it work on a day-by-day basis.

9. Do the establishment's records include multiple results that verify the monitoring of CCPs and conformance with critical limits?

10. Does the establishment have subsequent results that support the adequacy of corrective actions in achieving control at a CCP after a deviation from a critical limit has occurred?

B. What happens if the CSI determines that a noncompliance exists?

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. If the CSI determines that the hazard analysis does not meet the regulatory requirements, he or she should notify the DO for direction. The DO will provide direction to the CSI as to whether he or she should issue a 30-day reassessment letter, or the DO will institute an enforcement action as specified in the Rules of Practice, 9 CFR part 500 (see Chapter IV).

NOTE: An establishment is not required to respond in writing to the 30-day reassessment letter. It is, however, required to address the situation raised in the letter.

PART III -- Monitoring Requirement

A. What is the regulation that applies to monitoring?

9 CFR 417.2(c)(4) - *List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits*

B. How do CSIs verify the monitoring requirement?

CSIs verify the monitoring requirement by performing the HACCP 01 or HACCP 02 procedures. CSIs should use the thought process and methodology described below when performing either the HACCP 01 or HACCP 02 procedure. CSIs will verify the regulatory requirement by reviewing the HACCP plan, reviewing HACCP records, observing establishment employees performing monitoring activities, and taking measurements at the CCPs. In verifying the monitoring requirement, the CSI should seek answers to the following questions:

1. Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the CCPs to ensure compliance with the critical limits?
2. Are the monitoring procedures being performed as described in the HACCP plan?
3. Are the monitoring procedures being performed at the frequencies for the CCPs listed in the HACCP plan?

When seeking answers to the above questions, the CSI should:

a. Review the HACCP plan to determine whether the HACCP plan design includes the monitoring procedures and frequencies that are used to monitor the critical control points. Since the establishment can modify the HACCP plan without notifying inspection program personnel, the CSI should ensure that he or she is familiar with the monitoring procedures and frequencies in the HACCP plan by reviewing the HACCP plan each time he or she verifies the monitoring requirement. When reviewing the monitoring procedures and frequencies in the HACCP plan, the CSI should be able to understand exactly what the establishment is doing at the CCP. If the CSI does not understand how the establishment is performing the monitoring activity at the CCP, he or she will need to determine whether this is an indication that the monitoring requirement is not being met.

b. Observe an establishment employee performing the monitoring activities listed in the plan to determine whether the procedures are being executed as written in the HACCP plan.

c. Based on reviewing the monitoring records or on the basis of observing the establishment performing the monitoring procedures, determine whether the monitoring procedures are being performed at the frequencies specified in the HACCP plan.

C. What are some examples of monitoring noncompliance?

- The establishment is not conducting the monitoring procedures as specified in the HACCP plan.
- The establishment is not performing the monitoring procedures at the frequencies specified in the HACCP plan.
- The CSI takes a measurement at a CCP and finds that the critical limit is not met.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART IV -- Verification Requirement

A. What are the regulations that apply to verification procedures and frequencies?

9 CFR 417.2(c)(7) – *List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4 of this part.*

9 CFR 417.4(a)(2)(i)(ii)(iii) – *Ongoing verification activities include, but are not limited to: The calibration of process-monitoring instruments; direct observations of monitoring activities and corrective actions; and the review of records generated and maintained in accordance with § 417.5(a)(3) of this part.*

B. How do CSIs verify the verification requirement?

CSIs verify the verification requirement by performing the HACCP 01 or HACCP 02 procedures. CSIs should use the thought process and methodology described below when performing either the HACCP 01 or HACCP 02 procedure. CSIs will verify these regulatory requirements by reviewing the HACCP plan, reviewing HACCP records, and observing establishment employees performing verification activities. In verifying the verification requirement, the CSI should seek answers to the following questions:

1. Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments?
2. Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities and corrective actions?
3. Does the HACCP plan list procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3)?

4. Does the HACCP plan list product sampling as a verification activity?
5. Are process-monitoring instrument calibration activities conducted as per the HACCP plan?
6. Are direct observation verification activities conducted as per the HACCP plan?
7. Are records generated in accordance with 9 CFR 417.5(a)(3) being reviewed by the establishment?

When seeking answers to the above questions, the CSI should:

- a. Review the HACCP plan to determine whether it lists direct observation procedures and frequencies, records review procedures and frequencies, and process monitoring calibration verification procedures and frequencies. Since the establishment can modify the HACCP plan without notifying inspection program personnel, the CSI should ensure that he or she is familiar with the verification procedures and frequencies in the HACCP plan by reviewing the HACCP plan each time he or she verifies the verification requirement.
- b. Observe an establishment employee performing the verification activities listed in the plan to determine whether the procedures are being executed as written in the HACCP plan.
- c. Review the HACCP records or observe the establishment performing the verification procedures to determine whether the verification procedures are being performed at the frequencies specified in the HACCP plan.
- d. If the establishment has included an alternative generic *E. coli* sampling frequency into the HACCP plan (see 9 CFR 310.25(a)(2)(iv) or 381.94(a)(2)(iv)), the CSI will verify that the alternative is an integral part of the establishment's verification procedures for its HACCP plan.
- e. If product sampling is included in the HACCP plan, the CSI should observe an establishment employee taking samples and review the results as part of the HACCP 01 or 02 procedures. If the establishment received positive results, the CSI should verify the corrective action requirements of 9 CFR 417.3(b) are met.

NOTE: The CSI should use good judgment in recognizing that there are times when a HACCP plan might not contain all three ongoing verification activities listed in 9 CFR 417.4(a)(2)(i)(ii)(iii). If an establishment has a CCP that is monitored without the use of process monitoring equipment, there would be no need for process monitoring equipment calibration verification procedures. If an

establishment only has one employee, it would not be possible for that person to conduct a direct observation of the monitoring activity. In this situation, the HACCP plan would not need to list a direct observation of the monitoring activities. The direct observation ongoing verification activity should be designed for the plant verifier to directly observe the plant employee conducting the monitoring activity. A plant verifier conducting the same activity as the monitor does not meet the regulatory requirement for the direct observation verification activity described in 9 CFR 417.4(a)(ii).

C. What are some examples of verification noncompliance?

- The HACCP plan does not, at a minimum, list records review verification procedures; direct observation verification procedures; or calibration of process instruments verification procedures.
- The HACCP plan does not list the frequencies at which the verification procedures will be performed.
- The establishment is not performing the direct observation verification procedures as specified in the HACCP plan.
- The establishment is not performing the records review verification procedures as specified in the HACCP plan.
- The establishment is not performing the process monitoring verification procedures as specified in the HACCP plan.
- The establishment is not performing one or more of the verification procedures listed in the HACCP plan at the frequencies specified in the HACCP plan.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART V -- Recordkeeping Requirement

A. How do CSIs verify the recordkeeping requirements?

The CSI verifies that the establishment is meeting the recordkeeping requirements. The CSI will verify these requirements by reviewing the HACCP plan, hazard analysis, HACCP records, supporting documentation, and decisionmaking documents. The CSI verifies some of the recordkeeping requirements when performing the HACCP 01 procedure. For example, the CSI uses an 01 procedure to verify that the establishment has supporting documentation for the monitoring procedures in the HACCP plan. Other recordkeeping requirements are verified when performing the HACCP 02

procedure. Preshipment review is verified by performing 02 procedures. The majority of the time the CSI will verify the recordkeeping requirement by reviewing only records (recordkeeping component of the HACCP procedures). An occasion when a CSI may use the review and observation component to verify a recordkeeping requirement is when the CSI observes the establishment actually performing the pre-shipment review. The HACCP procedures that should be used for verification of the recordkeeping regulatory requirements will be specified throughout this section.

B. What is the regulatory requirement for recordkeeping?

9 CFR 417.2(c)(6) – *Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.*

C. How do CSIs verify compliance with 9 CFR 417.2(c)(6)?

The CSI should review the HACCP plan to verify that it lists the records the establishment will use to document the monitoring of the CCPs. The CSI should review the HACCP records to verify that the establishment is recording actual values and observations that were obtained during the monitoring activities. The CSI should verify these requirements when performing the HACCP 01 procedure and HACCP 02 procedure. In verifying this requirement, the CSI should ask the following questions:

1. Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP?
2. Do the records contain actual values and observations obtained during monitoring?

D. What are some examples of noncompliance?

- The HACCP plan does not provide for a recordkeeping system that documents the monitoring of the CCPs.
- The establishment is recording results with a check mark, rather than recording actual values and observations.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

E. What are the requirements for supporting documentation?

9 CFR 417.5(a) – *The establishment shall maintain the following records documenting the establishment's HACCP plan: (1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;*

(2) – The written HACCP plan, including decisionmaking documents associated with the selection and development of CCPs and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

NOTE: As part of the requirement above, establishments will have documentation that addresses the requirement in 9 CFR 417.4(a) that "every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis." The CSI should determine whether there is compliance with this regulation by verifying that the establishment has the documentation required in 9 CFR 417.5(a)(2)

F. How do CSIs verify compliance with these regulations?

CSIs should verify that there is compliance with these requirements by performing the HACCP 01 procedure. The CSI will verify these requirements by reviewing the hazard analysis, supporting documents for the hazard analysis, HACCP plan, decisionmaking documents associated with the selection and development of the CCPs and critical limits, supporting documentation for the verification procedures and frequencies, and supporting documentation for the monitoring procedures and frequencies. The CSI should use professional judgment on how much supporting documentation to request. The CSI should not just arbitrarily ask for supporting documents. The CSI should request supporting documents when he or she questions whether a decision made by the establishment is the appropriate one.

There are three possible outcomes for the verification of these requirements. Those three outcomes are compliance with the requirements, noncompliance with the requirements, and an inability to determine whether there is compliance because more information is needed. The HACCP 01 procedure is documented as performed when the requirements are met. The CSI issues an NR when there is noncompliance with the requirements. A 30-day reassessment letter should be issued to the establishment when there is not enough information available to determine whether the HACCP plan complies with 9 CFR 417.2. This provides the establishment with an opportunity to support the decisions made, or to reassess the hazard analysis and HACCP plan and make decisions that it can support.

In verifying these recordkeeping requirements, the CSI should seek answers to the following type questions:

1. Does the establishment have the supporting documentation for the decisions made in the hazard analysis?
2. Does the establishment have the decisionmaking documents associated with the selection of each CCP?
3. Do the documents explain why the establishment selected that location for the CCP?
4. Is there a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazards?
5. Does the establishment have scientific, technical, or regulatory support for the critical limit?
6. Does the support appear credible?
7. Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan?
 - a. If the CSI questions the monitoring frequencies, he or she should perform a monitoring check between the scheduled performances of the establishment's monitoring procedure.
 - b. If the CSI finds deviations, and the establishment has not, he or she should verify that the establishment addresses this issue.
8. Does the establishment have documents supporting the verification procedures and frequencies listed in the HACCP plan? Do the documents support what the establishment has done?
9. If the establishment has supporting documents for these decisions, does the documentation support the decisions?

G. What are some examples of noncompliance?

- The establishment has no supporting documentation to support why it is not necessary to establish controls for food safety hazards identified in the hazard analysis.
- The establishment has no decisionmaking documents associated with the selection of the CCPs.

- The establishment has no scientific, technical, or regulatory support for the critical limit.
- The establishment has no documentation supporting the monitoring procedures and frequencies.
- The establishment has no documentation supporting the verification procedures and frequencies.
- The establishment has documentation, but the documentation does not support the decisions made.

NOTE: There are situations when the CSI needs more information to determine whether the establishment is meeting the requirements of 9 CFR 417.2. If the establishment is monitoring its critical limit every hour, and the only supporting documents that are available are the monitoring records for the past year, the CSI might need more information to determine whether the HACCP plan complies with 9 CFR 417.2. The CSI could issue a 30-day reassessment letter requesting that the establishment reassess its HACCP plan. The CSI has not been trained in assessing the scientific and technical information that an establishment might have to support the HACCP system. The CSIs have resources available to assist them in evaluating this information. He or she can contact the TSC, or can contact the DO and request assistance from a CSO.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

H. What is the regulatory requirement for HACCP records?

9 CFR 417.5(a)(3) – *The establishment shall maintain: Records documenting the monitoring of CCPs and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.*

I. How do CSIs verify compliance with 9 CFR 417.5(a)(3)?

CSIs should verify these requirements by reviewing HACCP records that document the monitoring of CCPs and their critical limits, verification procedures and frequencies, and corrective actions taken in response to a deviation from a critical limit, a deviation not covered by a critical limit, or an unforeseen hazard. These requirements can be verified performing the HACCP 01 and HACCP 02

procedures. In verifying these requirements, the CSI should seek answers to the following questions:

1. Do the records document the monitoring of CCPs and their critical limits?
2. Do the records include actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan?
3. Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, and the date the record was made?
4. Are the verification procedures and results of those procedures documented?
5. Is the time recorded when the verification activity was performed?
6. Does the record contain the date the record was made?
7. Are the process-monitoring calibration procedures and results being recorded?

J. What are some examples of noncompliance?

- The records do not have the monitoring results recorded.
- The records do not include actual times that monitoring or verification activities are performed.
- The records include entries such as "acc", "ok", or check marks rather than actual values for monitoring results.
- The monitoring entries do not include product identification or code.
- The records do not include the date the record was completed.
- Initials being recorded rather than the verification procedures and results.
- The corrective actions taken in response to a deviation from a critical limit, other deviation, or unforeseen hazard are not recorded.
- The results of the calibration of process monitoring instruments are not recorded.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

K. What is the regulatory requirement for record authenticity?

9 CFR 417.5(b) – *Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.*

L. How do CSIs verify compliance with 9 CFR 417.5(b)?

CSIs should verify this regulatory requirement by reviewing HACCP records documenting the monitoring of CCPs and their critical limits, verification procedures and frequencies, and corrective actions taken in response to a deviation from a critical limit or deviation not covered by a critical limit or unforeseen hazard. When verifying this regulatory requirement, the CSI should seek answers to the following questions when performing the HACCP 01 or HACCP 02 procedure:

1. Was each entry on the record made at the time the event occurred?
2. Does each entry include the time?
3. Was each entry on the record signed or initialed by the establishment employee making the entry?

M. What are some examples of noncompliance?

- Some entries on the records do not contain the time the event occurred.
- The records do not include the signature or initials of the person performing the activity.
- There is no date on the records.
- Results are not being recorded when the events occur.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

NOTE: The HACCP monitoring records only need to have the date entered once on the form for all the entries made on that date.

N. What is the regulatory requirement for computerized records?

9 CFR 417.5(d) - *Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.*

O. How do CSIs verify compliance with 9 CFR 417.5(d)?

The CSI can verify this recordkeeping requirement by performing the HACCP 01 or HACCP 02 procedure. The CSI should verify this requirement by requesting that the establishment demonstrate the controls that it has in place to ensure the integrity of the records. When verifying this requirement, the CSI should seek the answer to the following question:

Are appropriate controls provided to ensure the integrity of electronic data and signatures?

P. What are some examples of noncompliance?

- The establishment does not have controls in place to ensure the integrity of the electronic records.
- The establishment has controls to ensure the integrity of the electronic records but is not following those controls, e.g., passwords and electronic signatures are not kept secure.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

Q. What is the regulatory requirement for record retention and availability?

9 CFR 417.5(e)(1)(2)- *Record retention. (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated products, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years. (2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.*

R. How do CSIs verify compliance with 9 CFR 417.5(e)(1)(2)?

The CSI should verify that the records are being maintained the required amount of time by reviewing the HACCP records. The CSI should not routinely request past records to verify that HACCP records are being maintained for the

appropriate time. If the CSI suspects that records are not being maintained for the required amount of time, he or she should contact the Front-line Supervisor for instructions. The CSI might request records stored off-site one time to ensure they can be provided, but it would not be necessary for the CSI to routinely request records that are stored off-site to verify this requirement. When verifying this recordkeeping requirement, the CSI should seek answers to the following questions performing the HACCP 01 or HACCP 02 procedure:

1. Are the records being maintained for the required amount of time, e.g., 1 year for slaughter and refrigerated products and 2 years for frozen, preserved, or shelf-stable products?

2. Are the records kept on-site for 6 months?

3. If the records are stored off-site after 6 months, can they be retrieved in 24 hours?

S. What are some examples of noncompliance?

- The establishment is not maintaining records for the required length of time.
- The records are not being maintained on premises for 6 months.
- The establishment cannot retrieve the records within 24 hours when stored off-site.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

T. What is the regulatory requirement for pre-shipment review?

9 CFR 417.5(c) – Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.

U. How do CSIs verify compliance with 9 CFR 417.5(c)?

FSIS considers product to be “produced and shipped” when the establishment completes pre-shipment review. Verifying that the establishment has completed pre-shipment review enables inspection program personnel to know whether the

company has taken full and final responsibility for applying its HACCP controls to the product that it has produced. The CSI should occasionally perform a verification check by observing the establishment employee perform the pre-shipment review. This type of observation is particularly important if the CSI is new to the establishment. Once the observation verification has been performed, this regulatory requirement can be verified using the recordkeeping component of the HACCP 02 procedure. The CSI should understand that pre-shipment review can be accomplished if the product is at a location other than the producing establishment, as long as the review of appropriate documents and compliance with 9 CFR 417.5(c) occurs before the product leaves the control of the producing establishment.

When verifying an establishment's pre-shipment review of its records by performing the HACCP 02 procedure, the CSI should seek answers to the following questions:

1. Has the establishment reviewed the records associated with the production of the product, prior to shipment?
2. Has the pre-shipment review been signed and dated by an establishment employee?

V. What are some examples of noncompliance?

- The establishment ships the product without conducting a pre-shipment review.
- The establishment performs pre-shipment review but does not sign and date the records.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART VI -- Corrective Actions

A. What is the regulation that applies to corrective actions taken in response to a deviation from a critical limit?

9 CFR Part 417.3(a) – *The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure: (1) The cause of the deviation is identified and eliminated; (2) The CCP will be under control after the corrective action is taken; (3) Measures to prevent recurrence are established; and (4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.*

B. How do CSIs verify compliance with 9 CFR 417.3(a)?

When there is a deviation from a critical limit, the CSI verifies that the requirements of 9 CFR 417.3(a) are met by comparing the corrective actions taken by the establishment to the requirements of the regulation. The CSI should verify that the corrective action requirements are met as part of the HACCP 01 and HACCP 02 procedures. The CSI can verify these requirements by using the recordkeeping component or the review and observation component of the procedures. The corrective action requirements should be verified every time a deviation occurs. To verify compliance with the corrective action regulatory requirements, the CSI seeks answers to the following questions:

1. Did the establishment identify the cause of the deviation?
2. Did the corrective action eliminate the cause?
3. Did the corrective actions ensure that the CCP is brought under control?
4. Were measures implemented to prevent recurrence of the deviation?
5. Did the actions ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce?

When seeking answers to these questions, the CSI should:

- a. Review the corrective action records associated with the deviation from the critical limit and observe the establishment executing the corrective actions.
- b. Compare the establishment's recorded corrective actions to the regulatory requirements listed in 9 CFR 417.3(a) to determine whether the corrective actions taken in response to the deviation from the critical limit meet all of these requirements.
- c. Observe the establishment executing the corrective actions to verify that the establishment has identified the appropriate affected product.
- d. Observe the establishment executing the corrective actions to verify that the establishment has identified and eliminated the cause of the deviation.
- e. Observe the establishment executing the corrective actions to verify that the establishment's corrective actions have the CCP under control after the actions are taken.
- f. Observe the establishment executing the corrective actions to verify that preventive measures are established.

g. Observe the establishment executing the corrective actions to verify that the establishment prevents product that is injurious to health or otherwise adulterated, as a result of this deviation, from entering into commerce.

C. What are some examples of noncompliance?

- The establishment did not identify the cause of the deviation from a critical limit.
- The establishment identified the cause of the deviation from the critical limit, but did not take appropriate actions to eliminate that cause.
- The establishment did not implement appropriate measures to ensure that the CCP is under control after the actions were taken.
- The establishment did not implement measures to prevent the recurrence of the deviation.
- The establishment did not take appropriate measures to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

D. What regulation applies when there is a deviation not covered by a specific corrective action or an unforeseen hazard occurs?

9 CFR 417.3(b) – *If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall: (1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met; (2) Perform a review to determine the acceptability of the affected product for distribution; (3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce; (4)...*

E. How do CSIs verify compliance with 9 CFR 417.3(b)(1)-(3)?

If an unforeseen hazard occurs, the CSI is to verify that the regulatory requirements of 9 CFR 417.3(b) are met by comparing the corrective actions taken by the establishment with the regulatory requirements in 9 CFR 417.3(b). The CSI should verify that these requirements are met each time there is a deviation not covered by specific corrective actions, or an unforeseen hazard

occurs. These requirements should be verified as part of the HACCP 01 or HACCP 02 procedures. The CSI should answer the following questions to determine whether the corrective action requirements have been met:

1. Did the establishment segregate and hold **all** affected product?

NOTE: To determine what product is affected, consider such factors as the pathogen of concern; the processing and packaging; the equipment; the establishment's testing under its HACCP plan; the establishment's HACCP plan monitoring and verification activities performed in accordance with 417.2 and 417.4; Sanitation SOP records as required in 416.16; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected.

2. Did the establishment perform a review to determine the acceptability of the affected product for distribution?

3. Did the establishment take necessary action with respect to the affected product to ensure that no product that is injurious to health, or otherwise adulterated as a result of the deviation, enters commerce?

4. Was a reassessment conducted to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan?

When seeking answers to these questions, the CSI should:

- a. Review the corrective action records associated with the deviation or unforeseen hazard and observe the establishment executing the corrective actions.

- b. Compare the establishment's recorded corrective actions to the regulatory requirements listed in 9 CFR 417.3(b)(1)(2)(3)(4) to determine whether the corrective actions taken meet all of these requirements.

- c. Observe the establishment segregating and holding the affected product to verify that the establishment segregated and held **all** affected product.

- d. Observe the establishment evaluating the affected product to verify that only acceptable product is released.

F. What are some examples of noncompliance?

- The establishment did not hold **all** affected product.

- The establishment held product, but it was not the product that was affected.
- The establishment did not evaluate the product to determine whether it was acceptable for distribution.
- The establishment evaluated the product and found it to be unacceptable for distribution, but did not take the necessary action to ensure that no product injurious to health or otherwise adulterated, as a result of this deviation, enters commerce.
- A reassessment was not conducted to determine whether the newly identified deviation or unforeseen hazard should be incorporated into the HACCP plan.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

G. What is the regulation that applies to reassessment when a deviation not covered in the HACCP plan, or an unforeseen hazard occurs?

9 CFR 417.3(b)(4) – Perform or obtain reassessment by an individual trained in accordance with § 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

H. How do CSIs verify compliance with 9 CFR 417.3(b)(4)?

The reassessment requirement cannot be randomly verified because reassessment occurs when something triggers it, e.g., a deviation not covered by a specific corrective action or an unforeseen hazard, etc. The establishment is required to document its reassessment when it is triggered by a deviation not covered by a specific corrective action or unforeseen hazard. The CSI should verify that the establishment is meeting the reassessment requirement by reviewing the corrective action records when a deviation not covered by a specific corrective action or unforeseen hazard occurs. When verifying compliance with 9 CFR 417.3(b)(4), the CSI should seek to address the following type questions:

1. Was a reassessment conducted as a result of an unforeseen hazard?
2. Does the establishment have supporting documentation for the decisions made during the reassessment?

I. What are some examples of noncompliance?

- A deviation not covered by a specific corrective action or an unforeseen hazard occurred, and a reassessment was not conducted.
- The establishment conducted a reassessment in response to a deviation not covered by a specific corrective action or an unforeseen hazard and determined that the newly identified deviation or unforeseen hazard should not be incorporated into the HACCP plan, but had no supporting documentation for that decision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

PART VII -- Reassessment Requirement

A. What is the regulation that applies to reassessment of the HACCP plan?

9 CFR 417.4(a)(3) – Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with § 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2(c) of this part.

B. How do CSIs verify compliance with 9 CFR 417.4(a)(3)?

The establishment is not required to document reassessments that are conducted as a result of changes in the process, unless the reassessment reveals that modification of the HACCP plan is necessary. If the reassessment reveals that modification of the HACCP plan is necessary, the HACCP plan must be modified immediately, and the HACCP plan must be signed and dated. The establishment is also required to sign and date the HACCP plan to demonstrate that the annual reassessment has been conducted. The CSI should review reassessment records, if available, and the HACCP plan to verify these requirements. When verifying compliance with 9 CFR 417.4(a)(3), the CSI should consider the following questions:

1. Has a reassessment been conducted to meet the annual reassessment requirement?

2. Did the establishment consider any significant developments that have occurred in the plant or that have occurred with respect to the types of products produced by the plant, in its analysis?

3. Has change occurred that could affect the hazard analysis or HACCP plan?

4. Did the establishment reassess?

5. If the reassessment revealed that the HACCP plan no longer meets regulatory requirements, was the HACCP plan modified immediately?

C. What are some examples of noncompliance?

- The annual reassessment was not conducted.
- Reassessment revealed that the HACCP plan no longer meets the requirements of 9 CFR 417.2(c), and the plan was not immediately modified.

NOTE: The establishment can reassess its HACCP plan any time during the calendar year to meet the annual reassessment requirement. This requirement does not require the establishment to reassess every 12 months. The CSI should verify the establishment is meeting the annual reassessment requirement somewhere close to the anniversary date of HACCP implementation in the establishment.

D. What regulation applies to reassessment of the hazard analysis?

9 CFR 417.4(b) – *Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.*

E. How do CSIs verify compliance with 9 CFR 417.4(b)?

The CSI will have to rely on his or her knowledge of the operation and the changes that occur within that operation. When verifying compliance with 9 CFR 417.4(b), the CSI must answer the following questions:

1. Does the establishment have a process without a HACCP plan because the hazard analysis has revealed there is no food safety hazard likely to occur?
2. Have any changes occurred in the process that could reasonably affect whether a food safety hazard exists?
3. If changes have occurred in the process, has a reassessment been conducted as a result of these changes?

F. What are some examples of noncompliance?

- The establishment has a process with no HACCP plan, changes occurred that could affect whether a food safety hazard exists, and the establishment did not conduct a reassessment of the hazard analysis.
- Changes occurred that could affect whether a food safety hazard exists, reassessment was conducted, the reassessment revealed that a food safety hazard exists, and no HACCP plan was developed.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

G. What regulations apply to reassessment after a B *Salmonella* set failure?

9 CFR 310.25(b)(3)(ii) or 381.94(b)(3)(ii) - *If the establishment fails to meet the standard on the next [second] series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product and take appropriate corrective actions.*

H. How do CSIs verify compliance with 9 CFR 310.25(b)(3)(ii) or 381.94(b)(3)(ii)?

If an establishment fails 2 consecutive *Salmonella* sets (B set failure), it must conduct a reassessment of the HACCP plan for that product. When the CSI is notified that the establishment failed to meet the standard on the second consecutive *Salmonella* set, he or she should verify that the establishment has reassessed its HACCP plan. The CSI should review the hazard analysis, HACCP plan, and supporting documents for the decisions made during

reassessment. When verifying compliance with 9 CFR 310.25(b)(3)(ii) or 381.94(b)(3)(ii), the CSI should seek answers to the following questions:

1. Was a reassessment conducted?
2. If a reassessment was conducted, did the establishment consider *Salmonella* a food safety hazard reasonably likely to occur in that process?
3. If the establishment did not consider *Salmonella* a food safety hazard reasonably likely to occur, does it have documentation to support this decision?

NOTE: CSIs will also work with other program personnel as described in Chapter III, *Salmonella* Performance Standards.

I. What are some examples of noncompliance?

- The establishment failed 2 consecutive *Salmonella* sets, and the HACCP plan was not reassessed.
- The HACCP plan was reassessed and *Salmonella* was not considered a food safety hazard likely to occur, but the establishment has no supporting documents for this decision.

CSOs

PART I – HACCP Assessment

A. What are the CSOs responsibilities for HACCP assessment?

The CSO performs comprehensive assessments of all food safety systems in operation. The focus of the comprehensive assessment is on the design of the food safety systems. For HACCP, the CSO will assess the design of the HACCP plans, microbiological testing protocols, and any other programs that will have an impact on food safety in the establishment.

After the CSO has assessed the systems individually, he or she determines whether the findings from one system correlate to the findings from another, such as investigating whether there is information from sanitation records indicating that there were sanitation problems on a RTE line on the day that the establishment collected a sample of product that tested positive for *L. monocytogenes*.

When the CSO has completed the comprehensive assessment in the establishment, he or she documents an Agency position. The CSO's report is e-mailed to the DO and the Front-line Supervisor. If the CSO finds that the HACCP system does not meet the requirements of 9 CFR 417.2 and 417.5 because of problems with its design or scientific basis, he or she will issue a 30-day reassessment letter to the establishment. If the problems are severe, the CSO may decide to draft an NOIE, for issuance by the DO, or recommend other enforcement actions described in the Rules of Practice, 9 CFR Part 500. The CSO will work with in-plant inspection program personnel to develop a verification plan for any new verification activities that might be necessary as a result of the comprehensive assessment and the corrective actions requested. The Front-line Supervisor will be e-mailed a copy of the verification plan if he or she is not available at the establishment. The Front-line Supervisor and the CSI should contact the CSO any time they have concerns about whether the corrective actions taken by the establishment are adequate to meet the HACCP requirements.

PART II -- Review of the Hazard Analysis

A. How do CSOs assess a hazard analysis?

CSOs will focus on the design of the hazard analysis to verify that it complies with the applicable regulatory requirements. The CSO's data collection and analysis will supplement and add scientific and technical weight to the verification of the in-plant team. The CSO should request records and information from the in-plant team about its verification of the hazard analysis. CSOs should verify

that the establishment has considered food safety hazards that can occur before, during, and after entry of product into the establishment. CSOs will use their scientific knowledge and professional expertise when reviewing the design of the hazard analysis to verify that the establishment has identified the appropriate food safety hazards and preventive measures for those hazards. Some questions that the CSO seeks answers for when reviewing the hazard analysis are:

1. Have the appropriate hazards been considered for the products produced?
2. Have the specific microbial, chemical, and physical hazards been identified that are prevalent to the specific products or process categories?
3. Are there any other hazards that would seem to be relevant that have not been considered?
4. Are the establishment's determinations about hazards that are reasonably likely to occur based on relevant historical data, scientific information, or technical information about the process and a clear understanding of the regulatory standard?
5. Are the controls that the establishment put in place validated, such as by repeated testing of the adequacy of the CCPs and critical limits, and review of records, to ensure that the hazard is prevented, eliminated or reduced to acceptable levels?

B. Have all potential sources of food safety hazards been considered?

The CSO should consider whether all potential sources of food safety hazards have been considered by the establishment, not merely those mentioned in 9 CFR 417.2(a)(3). In making that determination, the CSO should ask whether the establishment has considered and addressed the following questions:

1. Are any of the ingredients likely to present microbial, chemical, or physical hazards?
2. Does the food contain reworked product that might have different microbial, chemical, or physical characteristics than the original ingredients?
3. Does the food permit survival or multiplication of pathogens before or during preparation?
4. Is the product subject to recontamination after the kill step?
5. What is the normal microbial content of the food under proper storage conditions?

6. Under what circumstances will the normal microbial content of the food change?
7. Does the layout of the facility provide an adequate separation of raw materials from RTE food?
8. Will the equipment provide the time/temperature controls necessary for safe product?
9. Does the method of packaging affect the multiplication of microbial pathogens or the formation of toxins?
10. Can the sanitation practices that are employed affect the safety of the food that is being prepared?
11. Do the employees understand the food preparation process and the factors that they must control to ensure safe food?
12. What is the likelihood that the food will be stored at an appropriate temperature?
13. Is the food intended for consumption by a population with increased susceptibility to illness?
14. Will the preventive measures associated with each hazard “prevent, eliminate, or reduce to an acceptable level the hazards the establishment identified in the hazard analysis?”

C. How do CSOs assess the use of prerequisite programs?

When the CSO encounters a hazard analysis in which one or more identified food safety hazards are determined not reasonably likely to occur because of prerequisite programs, the CSO should request access to the prerequisite program as well as recent prerequisite program records to assess the effectiveness of these programs.

The CSO will review the description and features of the prerequisite program, including any supporting documents the establishment has for the criteria in the prerequisite program. The CSO should review such documents to determine whether they support the establishment’s decision that the hazard is not reasonably likely to occur.

The CSO will review data reflecting how the program has operated over a recent period of time and consider whether the control seems to be successful. The CSO should find that the records continue to support the decision that the

hazard is not reasonably likely to occur because of the presence of the prerequisite program.

If an establishment is producing raw ground beef products and has a prerequisite program based on the receipt of purchase specifications, the CSO should review the records associated with such a prerequisite program to verify that the documentation supports the decision made in the hazard analysis that *E. coli* O157:H7 is not reasonably likely to occur.

If the establishment is producing RTE products and has included product or environmental testing in a prerequisite program, the CSO should review the prerequisite program to verify that it is science-based. The CSO will assess the establishment's total system to verify that the establishment has designed its testing procedures so that if indicator organisms or *L. monocytogenes* are detected, the establishment has procedures in place to effectively address their presence. The CSO will review written procedures, assess decisionmaking documents for rationale, and review laboratory results.

The CSO will analyze this data to formulate an Agency position on whether the design of the prerequisite program is appropriate to address the decisions made in the hazard analysis. The CSO should ensure the prerequisite program is working in concert with all the other food safety programs when making this determination.

PART III -- Assessment of Monitoring

A. What does the CSO do to assess monitoring?

CSOs will perform data collection and analysis to verify that the design of the establishment's monitoring procedures, and the frequency with which it performs them, are adequate. The CSO should verify that the monitoring procedures describe a planned sequence of observations or measurements that are to occur at a CCP. The CSO should read the monitoring procedures in the HACCP plan and see whether he or she can visualize the monitoring activity that takes place at that CCP. Most monitoring procedures should be rapid because they relate to "real-time" processes.

The CSO should review a minimum of 60 days monitoring records to assist the CSO in obtaining the following information about the monitoring procedures and frequencies:

1. Are the monitoring frequencies in the HACCP plan continuous?
2. Would it be feasible to have continuous monitoring frequencies?
3. If the monitoring frequencies are not continuous, are they adequate to

demonstrate process control, e.g., statistically based, historically supported, etc.?

4. Is the basis of discontinuous monitoring frequencies documented and appropriate for the HACCP process being verified?

5. Does the establishment review monitoring records to detect trends that can be corrected before the loss of control? If so, the CSO should request to review these records.

6. If the basis for discontinuous monitoring frequencies is not documented, the CSO should determine whether the establishment has supported its frequencies as required by 9 CFR 417.5(a)(2), and if not appropriate, action should be taken, e.g., 30-day reassessment letter should be issued to the plant.

PART IV -- Assessment of Verification

A. How will CSOs assess compliance with the verification requirements?

While the CSI focuses on how an establishment is performing the verification activities outlined in its HACCP plan, CSOs will determine whether an establishment's on-going verification activities comply with regulatory requirements by focusing on the design of on-going verification activities. Consideration of design features should be based on a review of all the verification procedures associated with a single HACCP plan.

B. What records will the CSO review?

The CSO should review records that cover a minimum of 60 days of activity. The CSO should carefully review records of the CCPs, the surrounding verification procedures, the documents justifying their selection, and the frequency of their performance and then consider several analytic questions:

1. Are the verification procedures in the HACCP plan adequately designed for the establishment to determine whether the HACCP system is functioning as intended?

2. What do records reveal about performance at the CCPs?

3. Have there been deviations from critical limits?

4. If there were several deviations from critical limits, was there a reassessment and a new critical limit established? If not, does the establishment have documentation to support this decision?

5. If there were any deviations from critical limits at the CCP, how did the verification procedures contribute to improving the situation?

6. What do the records show about the results of verification?

7. Is the HACCP plan designed to include product testing as a verification procedure?

8. If product testing is a verification procedure listed in the HACCP plan, is this testing program science-based? The frequency and methodology of the testing should be supported in the science-based program (e.g., a rationale when product sampling is triggered—based on the results of food contact surface or environmental testing for an indicator organism; a rationale for sample size – 25 gram food sample; swab area size – along with a rationale for whether composite sampling on a daily or weekly basis is used; a rationale for product action based on indicator and pathogen testing results; a rationale for hold-and-test provisions if a food contact surface is positive for an indicator organism or pathogen). Is the testing designed in a manner to detect the organism of concern?

PART V -- Assessment Activities for Recordkeeping

A. How will CSOs review these recordkeeping activities?

The CSO will assemble the establishment's HACCP records, as specified in 9 CFR 417.5(a)(3) that cover a defined recent period of time.

Using establishment HACCP records only, the CSO should construct a summary of what happened, related to production of safe and wholesome products, in the establishment during that time.

The CSO should discuss with the in-plant inspection team and establishment what could be understood from the records. The in-plant inspection team and the establishment should discuss whether the records reflect what actually happened.

The CSO should also conduct an assessment of the scientific, regulatory, technical, or other supporting documentation. During the assessment of the records the CSO will seek answers to the following type questions:

1. Do the decisionmaking documents support the selection and development of CCPs and critical limits?

2. Do the supporting documents support both the monitoring and verification procedures selected and the frequency of those procedures?

3. Do the decisionmaking documents support the decisions made in the hazard analysis?

4. Does the establishment have documents to support the disposition of affected products?

5. Do the documents support the decisions made during reassessment?

6. If scientific documents are used to support decisions made, has the establishment demonstrated applicability to their in-plant environment?

PART VI -- Assessment of Corrective Actions

A. How do CSOs assess an establishment's corrective actions?

CSOs should select records from at least 60 days of activity to verify the establishment's corrective actions. They should focus the assessment on the design of the corrective actions. CSOs will select a variety of types of critical limits, the corrective actions planned when a deviation occurs and recent records of critical limits, deviations from critical limits, and the corrective actions.

The CSO should seek answers to the following type questions when verifying the corrective action requirement:

1. Did the corrective actions taken in response to a deviation from a critical limit meet the requirements of 9 CFR 417.3?

2. Did the corrective actions taken when a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, meet the requirements of 9 CFR 417.3(b)?

3. Have the corrective actions been effective, i.e., have they resulted in control at the CCP with respect to the critical limit from which there was a deviation? If the records do not demonstrate this control, it is difficult to conclude that the planned corrective actions have met regulatory requirements.

4. Have the preventive measures implemented in the establishment lessened the rate of the deviations from a critical limit?

PART VII -- Reassessment Activities

A. How do CSOs review reassessments?

The CSO should review a minimum of 60 days records to determine if there were situations that occurred that should have triggered a reassessment of the hazard analysis or HACCP plan.

If reassessment has occurred, the CSO should review the establishment's determination made based on the reassessment, and consider the following:

1. Did the establishment change its HACCP plan?
2. What was the basis for its decision?
3. Does it have decisionmaking documents to support making the change, or to support no change, as appropriate?
4. If a change was made, has the establishment validated the change?
5. Does it have supporting documents for the critical limit, the monitoring frequency, etc.?
 - For example, if the establishment produces raw beef products and conducted a reassessment considering the relevant scientific data, the CSO should ask the following questions:
 - a. If the establishment is producing trimmings for ground beef and tests the trimmings for *E. coli* O157:H7, does the establishment conduct a reassessment when a positive result is received?
 - b. Does the establishment producing the trimmings have documentation (scientific, technical) to support the decisions made during the reassessment that the controls in place are adequate to control *E. coli* O157:H7?
 - c. Has the establishment validated the modified HACCP plan by repeatedly testing the adequacy of the CCP, critical limits, monitoring, verification, recordkeeping procedures, and corrective actions set forth in the HACCP plan?
 - d. If the HACCP plan was modified to include microbiological sampling as a verification activity on the effectiveness of the interventions, is the sampling program statistically valid?
 - e. If the establishment did not modify its hazard analysis or HACCP plan as a result of the reassessment, does the establishment have documents to support this decision?
 - If the establishment receives raw beef for grinding and conducted a reassessment considering the relevant scientific data, the CSO should seek answers to the following type questions:
 - a. Does the receiving establishment have purchase specifications requiring all suppliers that determined *E. coli* O157:H7 as a hazard reasonably likely to occur to have one or more CCPs that are validated to eliminate or to reduce *E. coli* O157:H7 below detectable levels, and that verify that these specifications are met?

b. If the establishment considered *E. coli* O157:H7 as a hazard likely to occur in the grinding process, are the CCPs designed to control the pathogen?

c. If the establishment decided that *E. coli* O157:H7 is not a hazard likely to occur because this pathogen is addressed in prerequisite programs, does the establishment maintain documents setting out the procedures of the prerequisite program and related records as part of the decisionmaking documents?

- If the establishment is producing RTE products, the CSO should review the control measures included in the HACCP plans, Sanitation SOPs, or prerequisite programs. The CSO will review the written procedures, assess decisionmaking documents for completeness and rationale, and review laboratory results. The CSO should seek answers to the following type questions:

a. Has the establishment designed a written science-based program as part of the HACCP plan, Sanitation SOP, or prerequisite program?

b. If the establishment has testing procedures in place for indicator organisms or *L. monocytogenes*, does the establishment have in place procedures to effectively address their presence?

c. If the establishment has testing procedures in place for indicator organisms or *L. monocytogenes*, does the establishment increase its monitoring or verification sampling when significant construction occurs?

d. If the establishment is using an anti-microbial agent in the product in the final packaging to prevent *L. monocytogenes* growth, does the establishment have data to validate it is effective against *L. monocytogenes*?

e. If the establishment has a post-lethality treatment applied, does the establishment have data to validate it is effective against *L. monocytogenes*?

If the CSO observes execution problems during the comprehensive food safety assessment, he or she should document those in the Comprehensive Food Safety Assessment report.

CHAPTER III TABLE OF CONTENTS PATHOGEN REDUCTION ACTIVITIES

TOPIC	PAGE
Part I E. coli Testing	III-1-2
CSIs	III- 3-9
Part I General Procedures for E. coli Testing	III-3
Part II Sample Collection	III-4
Part III Sampling Frequency	III-5-7
Part IV Sample Analysis	III-7
Part V Recording of Test Results	III-8
Part VI Evaluation of Results	III-9
CSOs	III-10-11
Part I Assessment of Establishment E. coli Testing Process	III-10-11
Salmonella Performance Standards	III-12-15
Part I Salmonella Set Failures	III-12-15
A Set Failure	III-12-13
B Set Failure	III-13-15
C Set Failure	III-15

CHAPTER III - PATHOGEN REDUCTION ACTIVITIES

PART I -- *E. coli* Testing

The purpose of generic *E. coli* testing is to verify the effectiveness of sanitation and process control in slaughter facilities. The following discussion explains how inspection program personnel are to verify that the establishment is maintaining such controls.

A. What is the general requirement for *E. coli* testing?

Section 310.25 states: (a) *“Criteria for verifying process control; E. coli testing.*

- (1) Each official establishment that slaughters livestock must test for Escherichia coli Biotype 1 (E. coli). Establishments that slaughter more than one type of livestock or both livestock and poultry, shall test the type of livestock or poultry slaughtered in the greatest number. The establishment shall:*
 - (iii) Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.*
- (2) Sampling requirements.*
 - (i) Written procedures. Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address locations(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedures shall be made available to FSIS upon request.*
- (4) Recording of test results. The establishment shall maintain accurate records of all test results, in terms of CFU/cm² of surface area sponged or excised. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of livestock slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.”*

B. How will Front-line Supervisors verify the basic requirement of these regulations?

At the time an establishment is granted inspection, the Front-line Supervisor will verify that the written *E. coli* testing procedures meet the basic regulatory requirements. The Front-line Supervisor completes the *E. coli* Basic Compliance Checklist (FSIS Form 5000-3) when performing the 05A01 procedure. This procedure is only performed once. When the procedure is performed, the Front-line Supervisor should use this checklist to verify the written procedures meet the regulatory requirements:

1. Do the written procedures contain procedures for collecting samples for *E. coli* testing?
2. Do the written procedures identify the establishment employee designated to collect the samples for *E. coli* testing?
3. Do the written procedures address the location of sampling?
4. Do the written procedures describe how sampling randomness is achieved?
5. Do the written procedures describe how the samples are handled to ensure sample integrity?
6. Is the establishment collecting samples for *E. coli* testing?
7. Is the establishment recording the analytical results of *E. coli* tests on a process control chart or table?

NOTE: If the Front-line Supervisor performs the 05A01 procedure and determines that the *E. coli* written procedures do not meet regulatory requirements, he or she should meet with establishment management to inform them that they need *E. coli* testing procedures. If the establishment fails to adequately respond to the Front-line Supervisor's request, he or she should contact the DO to inform them of the situation. If there are changes to existing procedures, inspection program personnel are to notify the Front-line Supervisor.

CSIs

PART I – General Procedures for E. coli Testing

A. What general procedures will CSIs follow?

Each official establishment that slaughters livestock or poultry is required to test for *Escherichia coli* Biotype 1. There are 2 procedures (05A01 and 05A02) that CSIs use to verify that these establishments meet the *E. coli* regulatory requirements. The basic regulatory requirements are in 9 CFR 310.25(a)(1) – (4) for livestock slaughter establishments. The basic regulatory requirements for poultry slaughter establishments are set out in 9 CFR 381.94(a)(1) – (4). The regulatory requirements for livestock will be used in this document when the livestock and poultry regulations are the same. When there are differences in the regulations, both regulations will be listed. If CSIs find noncompliances while carrying out the methodologies below, they are to follow the noncompliance determination and documentation instructions in Chapter IV of this document.

B. How will the CSI verify the on-going compliance with 9 CFR 310.25(a)?

The CSI will verify all other requirements when performing the 05A02 procedure. The CSI will utilize FSIS Form 5000-4 to verify that these regulatory requirements are met.

C. How do CSIs verify that establishments are collecting samples from the correct type of livestock or poultry?

When verifying the sample collection requirements, the CSI will seek an answer to the following question: Is the establishment collecting samples from the type of livestock or poultry that it slaughters in the greatest numbers?

D. What is an example of noncompliance?

- The establishment slaughters pork in the greatest numbers but is collecting samples from beef carcasses.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART II – Sample Collection

A. What regulations apply to sample collection?

Paragraph 310.25(a)(2)(ii) states: Sample collection. *The establishment shall collect samples from all chilled livestock carcasses, except those boned before chilling (hot-boned), which must be sampled after the final wash. Samples must be collected in the following manner; (A) For cattle, establishments must sponge or excise tissue from the flank, brisket and rump, except for hide-on calves, in which case establishments must take samples by sponging from inside the flank, inside the brisket, and inside the rump. (B) For sheep, goat, horse, mule, or other equine carcasses, establishments must sponge from the flank, brisket, and rump, except for hide-on carcasses, in which case establishments must take samples by sponging from inside the flank, inside the brisket, and inside the rump. (C) For swine carcasses, establishments must sponge or excise tissue from the ham, belly and jowl areas.*

Paragraph 381.94(a)(2)(ii) states: Sample collection. *A whole bird must be taken from the end of the chilling process. If this is impracticable, the whole bird can be taken from the end of the slaughter line. Samples must be collected by rinsing the whole carcass in an amount of buffer appropriate for that type of bird. Samples from turkeys also may be collected by sponging the carcass on the back and thigh.*

B. How will the CSI verify these regulations?

When verifying these requirements, the CSI will seek answers to the following questions:

1. Is the establishment collecting samples at the required location in the process?
2. Is the establishment collecting samples by sponging or excising tissue from the required sites on a livestock carcass, or whole-bird rinsing a chicken or turkey carcass, or sponging a turkey carcass?

C. What are some examples of noncompliance?

- The establishment is not collecting samples from chilled carcasses, and the establishment is not hot boning.
- The establishment is sponging tissue from areas of the carcass other than the flank, brisket, and rump.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART III – Sampling Frequency

A. What are the regulations that apply to sampling frequency?

Paragraph 310.25(a)(1)(i) states: Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

Paragraph 310.25(a)(2)(iii) states: Sampling frequency. Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, must take samples at a frequency proportional to the volume of production at the following rates:

Cattle, sheep, goats, horses, mules and other equines: 1 test per 300 carcasses, but at a minimum of one sample during each week of operation.

Swine: 1 test per 1,000 carcasses, but at a minimum of one sample during each week of operation.

Paragraph 381.94(a)(2)(iii) states: Sampling frequency. Slaughter establishments except very low volume establishments defined in paragraph (a)(2)(v) of this section, must take samples at a frequency proportional to the establishment's volume of production at the following rates:

Chickens: 1 sample per 22,000 carcasses, but a minimum of one sample during each week of operation.

Turkeys, ducks, geese, and guineas: 1 sample per 3,000 carcasses, but a minimum of one sample during each week of operation.

Paragraph 310.25(a)(2)(iv) states: Sampling frequency alternatives. An establishment operating under a validated HACCP plan in accordance with §417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,

(B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

Paragraph 310.25(a)(2)(v) states: Sampling in very low volume establishments.

(A) Very low volume establishments annually slaughter no more than 6,000 cattle, 6,000 sheep, 6,000 goats, 6,000 horses, mules or other equines, 20,000

swine, or a combination of livestock not exceeding 6,000 cattle and 20,000 total of all livestock. Very low volume establishments that collect samples by sponging shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments collecting samples by excising tissue from carcasses shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

Paragraph 381.94(a)(2)(v) states: Sampling in very low volume establishments.

(A) Very low volume establishments annually slaughter no more than 440,000 chickens or 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas or a combination of all types of poultry not exceeding 60,000 turkeys and 440,000 birds total. Very low volume establishments that slaughter turkeys, ducks, geese or guineas in the largest number must collect at least one sample during each week of operation, after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments slaughtering chickens in the largest number shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

B. How do CSIs verify compliance with these regulations?

When verifying these regulatory requirements, the CSI should seek answers to questions similar to the following:

1. Is the establishment collecting samples at the frequency specified in 9 CFR 310 (a)(2)(iv)?
2. If an establishment is operating under a validated HACCP plan that has substituted an alternative frequency, is the alternative frequency an integral part of the HACCP plan verification procedures?
3. Has FSIS notified the establishment in writing that the alternative frequency is inadequate to verify the effectiveness of process control?
4. If the establishment is sampling based on very low volume, does the volume of animals slaughtered meet the criteria for that sampling rate?

C. What are some examples of noncompliance?

- A swine slaughtering establishment that does not qualify as a very low volume plant is not sampling at the rate of 1 per 1,000 slaughtered or a minimum of one sample each week of operation.
- A chicken slaughtering establishment that does not qualify as a very low volume plant is not sampling at the rate of 1 per 22,000 slaughtered or a minimum of one sample each week of operation.
- An establishment that does not qualify as a very low volume plant is sampling at the rate specified for very low volume rate of slaughter.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART IV – Sample Analysis

A. What are the regulatory requirements for sample analysis?

Paragraph 310.25(a)(1)(ii) states: *Obtain analytic results in accordance with paragraph (a)(3) of this section.*

*Paragraph (a)(3) states: Analysis of samples. Laboratories may use any quantitative method for analysis of *E. coli* that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists) or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.*

B. How do CSIs verify compliance with these regulations?

When verifying these regulatory requirements, the CSI will seek an answer to the following question: Is the laboratory analyzing the samples using an AOAC Official Method or another method that meets the criteria in paragraph (a)(3)?

C. What is an example of noncompliance?

- The laboratory analyzing the samples is not using an AOAC-approved method to obtain analytic results of the *E. coli* samples.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART V – Recording of Test Results

A. What are the regulatory requirements for recording test results?

Paragraph 310.25(a)(1)(iii) states: *Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.*

Paragraph (a)(4) states: Recording of test results. The establishment shall maintain accurate records of all test results, in terms of CFU/cm² of surface area sponged or excised. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of livestock slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

B. How do CSIs verify compliance with this regulation?

When verifying these requirements, the CSI should seek answers to the following questions:

1. Does the establishment's process control chart or table show at least the most recent 13 *E. coli* results?
2. Does the establishment's process control chart or table express *E. coli* results in terms of CFU/cm² of surface area sponged or excised by type of livestock slaughtered, or CFU/ml of fluid by type of poultry slaughtered?
3. Is the establishment retaining records of test results for 12 months?

C. What are some examples of noncompliance?

- The establishment's process control chart or table does not show the most recent 13 *E. coli* results.
- The establishment's process control chart or table does not express *E. coli* results in CFU/cm² of surface area sponged or excised by type of livestock slaughtered, or CFU/ml of fluid by type of poultry slaughtered.
- The establishment is not retaining records of test results for 12 months.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART VI – Evaluation of Results

A. What is the regulatory table for the evaluation of results?

Table 1 – Evaluation of *E. coli* Test Result

Type of Livestock	Lower limit of marginal range	Upper limit of marginal range	Number of sample tested	Maximum number permitted in marginal range
	(m)	(M)	(n)	(c)
Cattle	Negative	100 CFU/cm ²	13	3
Swine	10 CFU/cm ²	10,000CFU/cm ²	13	3
*Chickens	100 CFL/ml	1,000 CFU/ml	13	3
*Turkeys	N.A. ^a	N.A.	N.A.	N.A.

^a Not available; values for turkeys will be added upon completion of data collection program for turkeys.

* This portion of the Table 1 was extracted from Table 1 of § 381.94(a)(5).

B. How do CSIs verify compliance with this regulation?

If an establishment is sampling for *E. coli* by excising tissue, CSIs should verify that the results comply with the table above. If an establishment is sampling for *E. coli* by sponging carcasses, CSIs should verify that the establishment is evaluating the test results using statistical process control techniques. The CSI should verify that establishments that slaughter turkeys evaluate *E. coli* test results using statistical process control techniques. When verifying these regulatory requirements, the CSI should seek answers to the following questions:

1. If Table 1 does not include applicable m/M criteria, is the establishment using statistical process control techniques to determine what variation in test results is within normal limits?

2. If Table 1 includes applicable m/M criteria, is the establishment determining whether it is operating within these criteria?

C. What are some examples of noncompliance?

- The establishment is sponging livestock carcasses and is not using statistical process control techniques to evaluate *E. coli* test results.
- The establishment slaughters turkeys and is not using statistical process control techniques to evaluate *E. coli* test results.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

CSOs

PART I -- Assessment of Establishment's *E. coli* Process?

A. What are the CSOs responsibilities?

The CSOs should assemble and review the following information:

1. The results of verification procedures conducted by the CSIs.
2. The written *E. coli* procedures.
3. Justification for an alternative sampling frequency, if applicable.
4. Laboratory information or assurances about methodology.
5. Records of recent test results.

The CSO may also verify elements of sampling procedures by observing establishment employees performing them, if practicable. The CSO should analyze this information and determine whether there is compliance with 9 CFR 310.25(a) (1) – (4) or 381.94(a)(1) – (4).

If there has been a recent verification procedure by the in-plant team, and the results from this verification are different from those of the CSO, the CSO should initiate a meeting to resolve these differences. The CSOs should collect test data results covering at least 60 days.

The CSO should review these data against the evaluation criteria, which may be m/M values or values established by statistical process control. If any of the criteria are not met, the CSO is to conduct further data collection and analysis to determine whether the Agency needs to take other action to ensure that all applicable provisions of the law are met.

If the CSO observes that the evaluation criteria are not met routinely, the testing records should be supplemented with records of fecal NRs or deviations from the zero tolerance critical limit for the same time period. If the Agency was sampling and testing for *Salmonella* during the 60-day period, the CSO should seek those results. If by chance the establishment's product was sampled and tested for *E. coli* O157:H7 or implicated in a recall during the same 60-day period, the CSO should seek those results as well.

The CSO should perform statistical tests to define any correlations among the assembled data sets. If there are no significant correlations, the CSO need not pursue this analysis any further. If there are significant correlations, the CSO needs to analyze them to determine whether regulatory requirements are being met.

Whether the data sets show significant correlations or not, if there were NRs for fecal contamination or deviations from fecal critical limits, shortly before or during the 60-day period, the CSO should seek the corrective action records for each such instance and verify them.

The CSO may want to discuss the generic *E. coli* testing results that do not meet the criteria with establishment officials, to see if they have any views about what might have caused them, and anything they may have done to improve the situation.

***Salmonella* Performance Standards**

PART I -- *Salmonella* Set Failures

The *Salmonella* performance standard is designed to verify that establishments are controlling pathogens in their operation. See FSIS Directive 10,011.1 for instructions on how FSIS inspection program personnel are to do sampling for *Salmonella*. The following discussion explains what will occur if an establishment fails a sample set.

A. What happens if there is an A set failure?

The DM will send a letter to the establishment with the following information:

1. The set completion date as listed on the PREP report,
2. class of product,
3. sample test results (e.g., number of samples analyzed and number of positive samples),
4. a statement that the establishment needs to take immediate action to meet the standard in accordance with sections 310.25(b)(3)(i) or 381.94(b)(3)(i) of the regulations,
5. a request for the establishment to respond to the SVMO/IIC with an explanation as to why it believes that it is operating in full compliance with the regulations or on what immediate actions it intends to take.

Within 30 days of the date of the DM's letter:

1. The SVMO/IIC will document the establishment's response to the DM's letter (i.e., corrective actions identified or an explanation of why the establishment believes that it is in compliance). The SVMO/IIC will maintain a copy of the documentation in the inspection files.
2. The Front-line Supervisor and SVMO/IIC will conduct and document an assessment of the establishment's HACCP and Sanitation SOP procedures and, where applicable, analyze data from the establishment's generic *E. coli* testing, focusing on the corrective and further planned actions by the establishment. The SVMO/IIC will maintain a copy in the inspection files.
3. The Front-line Supervisor and SVMO/IIC will develop, document, and implement a plan, using the 01 and 02 Sanitation SOP and HACCP procedure codes, to verify any corrective actions implemented by the establishment (verification plan). The SVMO/IIC will maintain a copy in the inspection files.

4. After the SVMO/IIC and Front-line Supervisor have completed the above documents, as needed, the Front-line Supervisor will forward them to the DM.

The Front-line Supervisor and SVMO/IIC will correlate with in-plant inspection program personnel to ensure the plan is understood and executed. Based on findings of the verification activities, enforcement actions, if warranted, will be taken in accordance with the rules of practice. The Front-line Supervisor will inform the DM about any necessary enforcement action.

The Front-line Supervisor, SVMO/IIC, and in-plant inspection program personnel will consult with the TSC for any needed assistance in data analysis or technical questions that may arise.

The DM should ensure that collection of samples for the B set begins immediately after an establishment has completed its corrective and preventive actions or within 60 days of the end of the A set unless he or she has agreed with the establishment that more time is needed for corrective and preventive actions to be implemented. The DM, in communication with the Front-line Supervisor and SVMO/IIC should make sure that the establishment is progressing in a timely manner with their actions.

B. What happens if there is a B set failure?

The DM will send a letter to the establishment with the specific sample information as discussed above. The letter will inform the establishment that FSIS expects the establishment to address its total food safety program by reassessing its HACCP plan for that product and taking the appropriate corrective and preventive actions and making any necessary corrective actions in its Sanitation SOPs.

The DM, in consultation with the Front-line Supervisor, SVMO/IIC, and inspection program personnel, will determine whether the establishment conducted proper reviews of its total food safety program, including a reassessment as defined under 9 CFR 417.4(a)(3), Reassessment of HACCP plans, and any necessary evaluation of the effectiveness of the Sanitation SOPs as defined in 9 CFR 416.14, Maintenance of Sanitation SOPs. The DM will issue an NOIE as set out in the rules of practice if the reassessment is not performed.

After the establishment has performed a reassessment, validated modifications to the plan, and reevaluated and modified as appropriate the Sanitation SOPs, the DM will initiate an IDV review, as set out in FSIS Directive 5500.1 paragraph X. As provided for in FSIS Directive 5500.1, a CSO will be a member of this IDV team. The DM will receive the report developed from the IDV, which contains the team's findings. The DM's designee will analyze the findings and make recommendations to the DM about how to proceed. Also, at this point

for grinding establishments, FSIS may decide to conduct an IDV at some or all of the establishment's suppliers.

The DM will make one of the following decisions:

1. If the establishment's actions addressing its total food safety program do not meet the requirements in the regulations, based on the analysis and the supporting information, the DM will issue an NOIE.

2. If the establishment's actions addressing its total food safety program raise concerns regarding the establishment's design and execution of the program, but the concerns do not lead to a determination that there are regulatory noncompliances, the DM will send a 30-day reassessment letter that outlines his or her concerns. The 30-day reassessment letter will ask the establishment to produce records (9 CFR 417.5(a), Records and 9 CFR 416.16, Recordkeeping Requirements) that address the concerns identified by inspection program personnel in the letter.

3. If the establishment's actions addressing its total food safety program in response to the IDV meet the requirements in the regulations, or if in response to the NOIE or the 30-day reassessment letter, the establishment provides adequate evidence that it has not failed to meet the requirements in the regulations, the DM will schedule a C set to verify the successful operation of the establishment's total food safety program.

The CSO will take the lead in developing a verification plan to be used by in-plant inspection program personnel to verify all modifications made by the establishment in response to the B set failure and, if warranted, to assess corrective actions and further planned actions provided in response to an enforcement action. The CSO will send a copy of the verification plan to the Front-line Supervisor and DM and a copy will be maintained in the inspection files at the establishment. The verification plan will be based on the Sanitation SOP and HACCP 01 and 02 inspection procedures.

The CSO, Front-line Supervisor, SVMO/IIC, and in-plant inspection program personnel will correlate to ensure the plan is fully understood and executed as intended.

The Front-line Supervisor will e-mail a report in a Word document to the DM each month on the findings of the verification activities until the establishment has passed the next *Salmonella* sample set.

The DM should ensure that collection of samples for the C set begins immediately after an establishment has completed its corrective and preventive actions or within 90 days of the end of the B set unless he or she has agreed with the establishment that more time is needed for modifications to be implemented.

The DM, in communication with the Front-line Supervisor and SVMO/IIC should make sure that the establishment is progressing in a timely manner with their actions.

C. What happens if there is a C set failure?

The DM will send a letter to the establishment with the specific sample information, as discussed above. The letter will inform the establishment that FSIS will instruct a CSO and a Compliance Officer to conduct a focused assessment of the establishment's total food safety program to investigate the reasons why, in light of previous reassessments and corrective actions, the establishment failed a C set. (NOTE: For slaughter operations, the DM will consult with Headquarters.)

The CSO and a Compliance Officer will focus their assessment on the reassessments and corrective and preventive actions that the establishment took after the B set failure, and on whether there is a basis in accordance with the rules of practice to find that the establishment's total food safety program is not adequate. The CSO and the Compliance Officer will consult with the SVMO/IIC and the Front-line Supervisor. If the establishment requests, the CSO and the Compliance Officer will meet with the establishment and provide it with an opportunity to present evidence as to why it believes that it has not failed to meet the requirements in the regulations. The Compliance Officer will begin to develop a case file for an enforcement action if warranted. This file should include any information presented at the meeting with the establishment. Also, at this point for grinding establishments, FSIS may decide to conduct an IDV at some or all of the establishment's suppliers.

Based on findings of the CSO and the Compliance Officer, the DM and officials from headquarters will determine what actions the Agency will take, including enforcement actions, in accordance with the rules of practice.

There may be rare instances in which, based on the CSO and Compliance Officer findings, the DM determines that the establishment should conduct an additional reassessment. In such cases, the DM will issue a 30-day reassessment letter, and program personnel will conduct in-plant verifications and follow-up verification testing will occur.

THE UNIVERSITY OF CHICAGO

DEPARTMENT OF CHEMISTRY

PHYSICAL CHEMISTRY

PHYSICAL CHEMISTRY

PHYSICAL CHEMISTRY

PHYSICAL CHEMISTRY

PHYSICAL CHEMISTRY

PHYSICAL CHEMISTRY

PHYSICAL CHEMISTRY

PHYSICAL CHEMISTRY

PHYSICAL CHEMISTRY

PHYSICAL CHEMISTRY

PHYSICAL CHEMISTRY

PHYSICAL CHEMISTRY

PHYSICAL CHEMISTRY

CHAPTER IV TABLE OF CONTENTS ENFORCEMENT

TOPIC	PAGE
CSIs	IV-1-15
Part I Instructions for FSIS Form 5400-4	IV-1-3
Part II Documenting SPS Non Compliance	IV-4
Lighting Trend Indicator	IV-4
Structural Trend Indicator	IV-4
Outside Premises Trend Indicator	IV-5
Product Based Trend Indicator	IV-5
Part III CSI Documentation Responsibilities For Sanitation SOP Non Compliance	IV-6
Monitoring Trend Indicator	IV-6
Corrective Action Trend Indicator	IV-6-7
Recordkeeping Trend Indicator	IV-7
Implementation Trend Indicator	IV-7
Part IV HACCP Noncompliance Determinations	IV-8-10
Monitoring Trend Indicator	IV-11
Verification Trend Indicator	IV-11
Corrective Action Trend Indicator	IV-11
Recordkeeping Trend Indicator	IV-11-12
Part V E. coli Noncompliance Determination	IV-12-13
Part VI Linking NRs	IV-13-15

CSOs IV-16-17

Part I Instructions for FSIS Form 5000-8 IV-16-17

Rules of Practice IV-18-25

Part I Enforcement Actions IV-18

Part II Regulatory Control Actions IV-18-20

Part III Withholding Actions and Suspensions IV-20-22

Part IV Notification IV-22-25

Part V Abeyance IV-25

CHAPTER IV - ENFORCEMENT

CSIs

PART I – FSIS Form 5400-4, Noncompliance Record (NR)

Noncompliance Records (NR) are the forms completed by inspection program personnel and issued to the establishment when there is a failure to comply with regulatory requirements. The following discussion explains how to complete an NR.

A. How are the blocks on the NR and NR Continuation Sheet completed in the PBIS Electronic format or in instances when the electronic format is not accessible, on the paper FSIS Forms 5400-4 and 5400-4a?

Type of noncompliance

Food Safety

Any 01 - SSOP

Any 03 - HACCP

06D01 – Sanitation Performance
Standards

05A01 - micro. sampling for *E. coli*

05A02 - micro. sampling for *E. coli*

05A03 - micro. sampling for *Salmonella*

05B02 - Directed sampling

05C01 - Residue

Other Consumer Protections

Any 04 - Economic/Wholesomeness

05B01 - Economic Sampling- Scheduled

06D02 – Inspection Requirements

BLOCK

1. **Date**--Enter the date noncompliance occurred. The date can be entered numerically, e.g., 1-29-02.

2. **Record No.**--Number the NRs completed in a given establishment sequentially, by year (i.e., 1-02, 2-02, 3-02, etc., for the paper forms regardless of who completes the NR).

3. **Est. No.**--Enter as a 5-digit number followed by a red meat or poultry designator and the shift number (e.g., 00345 M/2).

4. **To (Name and Title)**--Enter the name and title of the responsible establishment official. For a HACCP system noncompliance, always enter the name of the person who signed the HACCP plan. For a Sanitation SOP regulation noncompliance, always enter the name of the person who signed the

Sanitation SOPs. For SPS noncompliance, the CSI should enter the name of the establishment official responsible for responding to the NRs.

5. Personnel Notified--Enter the name of the establishment management personnel who was/were notified about the noncompliance.

6. Relevant Regulations--Cite the specific regulatory requirements that the establishment did not meet. For example, if the establishment did not take corrective action in response to a deviation from a critical limit, then 417.3 (a) would be entered.

7. Relevant Section/Page of Establishment Procedure/Plan—Enter the section or page of the establishment's procedure or plan when the noncompliance represents the failure to comply with the written provisions of their procedure or plan. For example, if the monitoring frequency listed in the HACCP plan is hourly, and the establishment performs the procedure every two hours, there is monitoring noncompliance. Inspection program personnel record the section or page of the HACCP plan that lists the monitoring frequency. Place an "X" in the appropriate box to reference the type of procedure or plan. *E. coli* and alternate processing procedure noncompliance are considered "other." When the noncompliance is not related to a procedure or plan, enter N/A.

8. ISP Code--Enter the code of the procedure performed (refer to: FSIS Directive 5400.5; Attachment 6, Inspection System Procedure Guide for a listing of codes).

9. Noncompliance Classification Indicators--Mark the classification trend indicator that best describes the noncompliance. This should be the same classification trend indicator that is circled when inspection program personnel complete the related FSIS Form 5400-2; Procedure Schedule. For basic compliance procedures (01A01, 03A01, and 05A01), no trend indicator is marked.

10. Description of Noncompliance—Describe each noncompliance in clear, concise terms, including the exact problem, its location, and the effect on product. For example, if the CSI observes condensation dripping from the ceiling onto exposed product, the description should include the area of the plant where the observation was made, what type of product was being contaminated, and the action taken. If there is a trend of noncompliance developing, and the current NR is linked to previous NRs, the CSI should list the previous NRs with the similar noncompliance from the same cause. The NR should state what corrective actions were proposed, and that these actions were ineffective or not implemented. If this developing trend has been discussed with establishment management, this information should also be documented in this block. If more space is needed to describe the noncompliance, use a NR Continuation Sheet.

11. Signature of Inspection Program Employee--The IIC or CSI signs the NR after blocks 1 through 10 have been completed.

12 & 13. Plant Management Response--The "immediate action" and "further planned action" blocks should be completed. When the establishment elects to respond, the "immediate action" is the action the establishment is taking to correct the noncompliance including appropriate product disposition. The "further planned action" is the action to prevent recurrence. Inspection program personnel should document an oral response by the plant management.

14 & 15. Signature of Plant Management and Date--If establishment management responds in writing on block 12 or block 13, an establishment official should sign and date the NR.

16 & 17. Verification Signature of Inspection Program Employee and Date --*The IIC or CSI signs after inspection program personnel have verified the establishment has brought itself into compliance with the regulatory requirement that resulted in the issuance of the NR and if necessary the NR Continuation Sheet.*

B. How can FSIS personnel write a good NR?

- Clearly and concisely identify each noncompliance. Be descriptive, specific and thorough, including time and location.
- Explain that the establishment management has received adequate oral and written notification.
- Include:
 - The inspection findings,
 - Any previous corrective actions that were unsuccessful, and
 - Any applicable deadlines.
- Set out the establishment response to previous notification.
- If a regulatory control action is taken, reflect the use.

C. How is the continuation sheet completed?

In addition to the NR, there is a Continuation Sheet, FSIS Form 5400-4a, that is used only when the inspection program personnel need extra space, or when multiple inspection program personnel conduct verification of pre-operational sanitation inspection procedures in elements 01B and 01C. When using the NR

Continuation Sheet for extra space, inspection program personnel can just check the box next to the word "Attachment" in the top right corner of the sheet, and complete blocks 1-3,10,11 and 12.

PART II -- Documentation of SPS Noncompliance

A. What are the general procedures for documenting the SPS verification activities?

The CSI performs ISP procedure 06D01 to verify compliance with the SPS regulations. Noncompliance is the failure of an establishment to meet one or more regulatory requirements. Every time the CSI finds that the establishment is not meeting the SPS requirements, he or she should document the noncompliance on an NR. If the noncompliance is failure by the establishment to comply with the SPS, the Food Safety block is checked on the NR.

There are four trend indicators associated with procedure 06D01. Those trend indicators are lighting, structural, outside premises, and product based. Only one of these trend indicators can be used for each NR issued. If more than one trend indicator applies, the CSI should use the most appropriate one to describe the noncompliance. If the determination has been made that there is regulatory noncompliance, the CSI should include the regulation citation in Block 6 of the NR.

B. When is the lighting trend indicator used?

The lighting trend indicator is used when there is noncompliance with lighting requirements. If inadequate light causes the quality or intensity of lighting to be inadequate to determine whether the products are being processed, handled, stored, or examined under sanitary conditions, and thus whether the product is not adulterated, the lighting trend indicator should be marked on the NR (see Chapter I, Part IV).

NOTE: The CSI should realize that there might be less than perfect situations that do not constitute noncompliance. If one light is inoperable, but its absence does not cause the intensity or quality of the lighting to be inadequate to determine whether the products are being processed, handled, stored, or examined under sanitary conditions, and thus whether the product is not adulterated, there is no noncompliance.

C. When is the structural trend indicator used?

The structural trend indicator is used when structural regulatory requirements are not met. The CSI should use the structural trend indicator when structural noncompliances are observed, such as holes in the wall, cracks or holes in the

floor, or condensation on overheads that create insanitary conditions or could result in product adulteration (see Chapter I, Part III).

D. When is the outside premises trend indicator used?

The outside premises trend indicator is used when the CSI finds that the regulatory requirements for outside premises are not met. For example, the CSI should use the outside premises trend indicator when he or she observes an accumulation of trash or rubbish outside the establishment that permits harborage and breeding of pests (see Chapter I, Part II).

E. When is the product based trend indicator used?

The product based trend indicator is used when there is noncompliance involving product that does not result in misbranding, mislabeling, or direct product contamination that is covered by the Sanitation SOPs. For example, the CSI observes product from the previous day's production on a wall before the start of operations that creates an insanitary condition, he or she should use the product based trend indicator (see Chapter I, Part XII).

F. What actions should be taken when noncompliance with the SPS regulations is observed?

If an establishment has not complied with a sanitation performance standard, and product is not directly contaminated, CSIs need to determine whether the noncompliance requires a regulatory control action to prevent contamination or adulteration of product.

1. If there is an imminent probability that the noncompliance will result in product adulteration if not addressed immediately, CSIs will take a regulatory control action such as tagging product or rejecting equipment and complete a NR.

2. If the noncompliance does not need immediate attention, CSIs are to notify the establishment management of the noncompliance and document the finding on a NR.

If an establishment has not complied with a sanitation performance standard, and product is directly contaminated, CSIs will verify that the establishment addresses the noncompliance by meeting the requirements of 9 CFR 416 or 9 CFR 417 as described below. CSIs will write an NR using the appropriate 01 (Sanitation SOP) or 03 (HACCP) ISP procedure code.

1. If direct product contamination occurs, CSIs will verify that the establishment implements corrective actions, including product control actions, that meet the requirements of 9 CFR 416.15. The establishment may need to re-

evaluate the effectiveness of its Sanitation SOPs and modify them if they are no longer effective in preventing direct contamination or adulteration of product.

2. If the direct product contamination poses a food safety hazard, CSIs will verify that the establishment implements corrective actions, including product control actions, that meet the requirements of 9 CFR 417.3(b). These corrective actions include a reassessment to determine whether the unforeseen hazard should be incorporated into the HACCP plan.

PART III -- Documentation of Sanitation SOP Noncompliance

A. What do CSIs document?

The CSI performs the Sanitation SOP verification procedures to verify that the establishment is meeting the regulatory requirements of 9 CFR 416.12 – 416.16. When the CSI determines that the establishment does not meet one of these regulatory requirements, he or she should document the noncompliance on an NR, marking the most appropriate trend indicator and the food safety box.

The four trend indicators for Sanitation SOP are:

1. monitoring,
2. implementation,
3. recordkeeping, and
4. corrective actions.

NOTE: Only one trend indicator should be used for each NR issued.

B. When is the monitoring trend indicator used?

The CSI should mark the monitoring trend indicator on the NR when he or she determines that the plant fails to monitor its pre-operational or operational sanitation procedures daily or at the frequency specified in the Sanitation SOP. When the CSI observes contaminated product or contaminated direct contact surfaces that the establishment monitoring did not detect, the monitoring trend indicator is used (see Chapter I, Part XIV).

C. When is the corrective action trend indicator used?

The CSI should mark the corrective action trend indicator when the establishment does not meet the corrective action requirements. This trend indicator should be marked on the NR when the establishment does not take corrective actions to meet the requirements in 9 CFR 416.15. This trend

indicator should be used when FSIS determines that the corrective actions taken are not adequate to restore sanitary conditions. It would be the appropriate trend indicator to use if the establishment did not implement measures adequate to prevent recurrence. If the establishment did not implement corrective action to ensure appropriate disposition of contaminated product, this would be the appropriate trend indicator (see Chapter I, Part XVI).

D. When is the recordkeeping trend indicator used?

The CSI should use the recordkeeping trend indicator when there is noncompliance with 9 CFR 416.16. This trend indicator would be marked when the records are not being maintained daily or retained for the required period of time, or the plan fails to record the results of the monitoring check. This is the appropriate trend indicator to use when the establishment is not documenting the corrective actions taken when FSIS or the establishment determines the Sanitation SOP did not prevent direct contamination or adulteration of product. This trend indicator would also be marked on the NR when the records have not been initialed and dated (see Chapter I, XVII).

E. When is the implementation trend indicator used?

The CSI uses the implementation trend indicator when he or she finds two regulatory requirements that have not been met during the performance of one procedure. For example, if the CSI is performing the 01C02 procedure and finds that the establishment is not monitoring the operational procedures at the stated frequency and did not initial and date the daily sanitation records, the appropriate trend indicator to use is implementation.

F. What actions do CSIs take when noncompliance with the Sanitation SOPs is observed?

When the CSI is performing the 01B02 or 01C02 Sanitation SOP procedure and observes direct contact surfaces or product that is contaminated, he or she should take a regulatory control action on the equipment or product. He or she should not remove the regulatory control action until the establishment has proposed corrective actions that 1) ensure appropriate disposition of products, 2) restore sanitary conditions, and 3) prevent recurrence of direct contamination or adulteration of products. The CSI documents the noncompliance on the NR. If the CSI is performing the 01B01 or 01C01 Sanitation SOP procedure and observes that the establishment official responsible for the implementation and monitoring of the Sanitation SOP did not initial and date the record, the CSI documents the noncompliance on the NR, although no regulatory control action would be required.

NOTE: If the establishment has found the noncompliance and taken the corrective actions required, there is no noncompliance. The CSI should verify

that the establishment is implementing the corrective actions specified in 9 CFR 416.15 when the establishment finds direct contamination or adulteration of products or contact surfaces. If the establishment finds that the responsible individual did not initial and date the record and implemented immediate and further planned actions and records these actions, the CSI should not document this as noncompliance.

G. What actions do CSIs take when noncompliance is found with both SPS and Sanitation SOP regulatory requirements?

If the CSI is performing one of the sanitation procedures (06D01, 01B02, 01C02) and observes noncompliance with the SPS and Sanitation SOP regulatory requirements, all of the findings would be documented under the appropriate Sanitation SOP procedure. If the CSI is performing the 01B02 or 01C02 procedure and only observes noncompliance with the SPS regulations, he or she should document the Sanitation SOP procedure as performed on the Procedure Schedule, and issue a NR under the 06D01 procedure. If the CSI is performing the 06D01 procedure and only observes Sanitation SOP noncompliance, he or she should document the 06D01 procedure as performed and issue a NR for the Sanitation SOP noncompliance using the appropriate procedure (01B02 or 01C02).

PART IV -- HACCP Noncompliance Determinations

A. What is the difference between a deviation from a critical limit and HACCP noncompliance?

A deviation from a critical limit is the failure to meet the applicable value determined by the establishment for a CCP. If a deviation from a critical limit occurs, an establishment is required to take actions in accordance with 9 CFR 417.3.

A HACCP noncompliance is the failure to meet any of the regulatory requirements of 9 CFR part 417, monitoring, verification, recordkeeping, reassessment, and corrective action. If a HACCP noncompliance occurs, an establishment is expected to take immediate and further planned actions to correct the noncompliance.

B. What should CSIs consider before making a noncompliance determination?

Before making a determination that there has been noncompliance, consider the following questions:

1. Has the establishment already identified the failure to meet the regulatory requirements or deviations from critical limits?

2. If product is involved, has the establishment ensured product safety?

3. Has the establishment taken immediate and further planned actions to correct the failure to meet regulatory requirements, or has it taken the 9 CFR 417.3 corrective and preventive measures to address the deviations?

4. Is a trend developing (i.e., has the establishment repetitively carried out the actions in 1 through 3 above for similar situations)?

NOTE: In answering these questions, it may be necessary to consider additional records.

If the answer is no to questions 1, 2, or 3, or yes to question 4, then a noncompliance exists. CSIs will write an NR and perform a HACCP 02 procedure.

If the answer is yes to 1 through 3 and no to question 4, then there is no noncompliance because the establishment has already identified and addressed the situation. The HACCP 01 should be considered performed, and no other action is necessary. Because the establishment's response provides the further planned actions and preventive measures for the noncompliance or deviation, not writing an NR does not adversely affect an inspection program employee's ability to track developing trends. However, an establishment's failure to follow through on further planned actions and preventive measures could lead to recurring noncompliances and would warrant NRs in recurring situations.

C. What are some situations that CSIs may encounter that will require a determination as to whether there is a noncompliance?

NOTE: For purposes of consistency, all the examples below use a monitoring example. The methodology applies to problems with verification, recordkeeping, reassessment and corrective actions as well.

EXAMPLE 1: While performing the HACCP 01 procedure records review, an inspector finds that an establishment employee missed a 9:00 a.m. monitoring check. The inspector then finds that the establishment found the error during its records verification, demonstrated product safety with other records, and took immediate corrective and preventive measures for the noncompliance by re-training the employee. Also, the inspector looked at previous NRs and determined that the establishment had not missed a monitoring check in over three months. In this situation no NR is necessary even though there was a missed monitoring check, and the HACCP 01 procedure is marked as performed. However, if the inspector finds that adequate preventive measures were not in place, and that the missed monitoring check and correction had occurred several times within the month, he or she may determine that a trend for monitoring

noncompliance has developed. In this case he or she will issue an NR and discuss this trend with establishment management during the weekly meeting.

EXAMPLE 2: While performing the HACCP 01 procedure records review, an inspector finds that an establishment employee missed a 9:00 a.m. monitoring check and finds no indication that the establishment identified the missed monitoring check. He or she writes an NR for the HACCP 01 procedure. Then he or she performs a HACCP 02 procedure and finds that the product was shipped without a pre-shipment review. In this situation the inspector writes an NR that explains this noncompliance. Next he or she determines whether the establishment can provide other documentation that establishes product safety. If the establishment cannot demonstrate product safety, the inspector would take action under the Rules of Practice, 9 CFR part 500.

EXAMPLE 3: While performing the HACCP 01 procedure records review, an inspector observes that an establishment employee recorded a deviation from a critical limit on the monitoring record. The inspector verifies that the corrective actions taken by the establishment meet the requirements of 9 CFR 417.3(a). There is no regulatory noncompliance, and an NR is not necessary.

EXAMPLE 4: While performing the HACCP 02 procedure records review for a single lot of product, an inspector sees in the records that an establishment employee missed a monitoring check at 10:00 a.m. and had a deviation from a critical limit at 11:00 a.m. The inspector continues to review the records and finds that at pre-shipment review the establishment identified the deviation and took the proper 9 CFR 417.3 corrective and preventive measures but failed to address the monitoring error. In this situation the inspector writes an NR for the monitoring error and determines whether the establishment can demonstrate product safety relevant to the missed monitoring check. If so, no other action is necessary. If the establishment cannot support product safety, the inspector should take action in accordance with the Rules of Practice, 9 CFR part 500.

D. How do CSIs document a HACCP noncompliance?

The CSI performs the HACCP verification procedures to verify that the establishment is meeting the regulatory requirements of 9 CFR 417.2 – 417.7. The five requirements that the CSI verifies when performing these procedures are **monitoring, verification, corrective actions, recordkeeping, and reassessment**. When the CSI performs one of the HACCP procedures and determines that there is regulatory compliance, he or she documents that the procedure is performed on the procedure schedule. When the CSI determines that the establishment does not meet one of the regulatory requirements, he or she documents the noncompliance on an NR, marking the appropriate trend indicator. The four trend indicators for HACCP are monitoring, corrective action, recordkeeping, and establishment verification. Only one trend indicator should be used for each NR issued.

E. When do CSIs use the monitoring trend indicator?

A CSI should use the monitoring trend indicator when he or she determines that there is noncompliance with the monitoring requirement. This trend indicator should be marked: 1) if the CSI determines the establishment is not monitoring the critical limit at the frequency stated in the HACCP plan; 2) if the CSI determines the establishment is not monitoring the critical limit using the procedures described in the HACCP plan; or 3) if the CSI finds a deviation from the critical limit that the establishment has no way of detecting (see Chapter II, Part III).

F. When do CSIs use the verification trend indicator?

The CSI should use the establishment verification trend indicator when: 1) the establishment is not conducting the verification activities as described in the HACCP plan, or 2) the establishment is not conducting the verification activities at the frequencies described in the HACCP plan (see Chapter I, Part IV).

G. When do CSIs use the corrective action trend indicator?

The corrective action trend indicator should be used when a deviation or an unforeseen hazard occurs, and the corrective action taken by the establishment does not meet the regulatory requirements. The CSI should use the corrective action trend indicator if the corrective actions taken in response to a deviation from a critical limit did not: 1) appropriately address identifying and eliminating the cause of the deviation; 2) include measures to ensure that the CCP is under control; 3) include measures to prevent the deviation or unforeseen hazard from recurring; or 4) include appropriate disposition of the product (see Chapter I, Part VI).

NOTE: For this trend indicator, the CSI is only to document an establishment's failure to meet the requirements of 9 CFR 417.3. If the establishment finds the deviation or unforeseen hazard and takes the corrective action necessary to meet the regulatory requirements, there is no noncompliance.

H. When do CSIs use the recordkeeping trend indicator?

The CSI should use the recordkeeping trend indicator when: 1) The monitoring records do not include the actual times, temperatures, or other quantifiable values, the calibration of process-monitoring instruments, corrective actions, verification procedures and results, product identity, signature or initials of the person making the entry, or the date the record is made; 2) the establishment does not have the decisionmaking documents associated with the selection and development of the CCPs and critical limits, and documents

supporting both the monitoring and verification procedures and frequencies; 3) the establishment did not conduct pre-shipment review; or 4) the establishment is not retaining HACCP records for the required length of time (see Chapter I, Part V).

PART V -- *E. coli* Noncompliance Determination

A. How do the CSIs determine noncompliance?

When the CSI performs the 05A02 procedure (see Chapter III), noncompliance exists if he or she determines that:

1. The establishment is not collecting samples from the type of livestock or poultry that it slaughters in the greatest number.
2. The establishment is not collecting samples at the location in the slaughter process required by the regulations.
3. The establishment is not collecting samples by sponging or excising tissue from the required sites on a livestock carcass, whole-bird rinsing or sponging on the required sites of a turkey carcass or whole-bird rinsing chickens.
4. The establishment is not collecting samples at the required frequency.
5. The establishment is not sampling randomly as per its written procedure.
6. The establishment is not having the samples analyzed at a laboratory using an AOAC Official Method or another method that has been approved and published by a scientific body.
7. The establishment's records of test results do not include at least the most recent thirteen test results.
8. The establishment's records do not express *E. coli* test results in terms of colony forming units per square centimeter when excision tests are used for cattle and swine or sponge tests are used for cattle, swine, or turkeys; or test results are not expressed in colony forming units per milliliter when the whole bird rinse method is used.
9. The establishment is not retaining records of test results for twelve months.
10. Table 1 in the regulations does not include applicable m/M criteria, and the establishment is not using a statistical process control technique to determine how much variation in test results is within normal limits.

11. Table 1 in the regulations includes applicable m/M criteria, and the establishment is not determining whether it is operating within these criteria.

B. How will the CSI document findings?

When the CSI makes the determination that one or more of the above requirements are not met, the CSI should document the noncompliance on an NR. The "other" trend indicator is always used with the 05A02 procedure.

PART VI -- Linking NRs

A. When should NRs be linked?

The CSI should only link NRs when the noncompliances are from the same cause. For example:

- If repetitive condensation findings are occurring, the CSI should be linking NRs together to document that there is a trend occurring. This trend may be because the preventive measures are either not implemented or are ineffective in preventing this noncompliance. However, a CSI should use professional judgment in making the determination whether NRs should be linked. If the establishment has shown a substantial period of compliance, the CSI should not link the NR to previous NRs with the same cause, unless there is a compelling circumstance that justifies doing so, for example, the exact same circumstance that brought about the initial NR has reoccurred.
- An NR under procedure 06D01 for condensation can be linked to an NR written for condensation under procedure 01B02 or 01C02 as the cause is the same. However, an NR written for condensation under 06D01 should not be linked to an NR written for water dripping from the ceiling, from a roof leak, under 06D01. They are both noncompliances and both are water dripping from the ceiling. Both are documented under the same procedure code and the same trend indicators. However, the noncompliance for condensation is from a different cause than the noncompliance for the roof leak.

When the CSI links one NR to another, he or she should reference the previous NR number and date as well as the further planned action that was ineffective in preventing recurrence of the noncompliance. For example:

- The CSI issued NR 25-02 on July 1, 2002, for condensation and the establishment installed fans as its further planned action. On July 8, 2002, the CSI again observes condensation. If the CSI links these NRs, he or she should document in Block 10, that the same or similar noncompliance was documented on July 1, 2002, on NR 25-02. The further planned

action of installing fans was ineffective in preventing the condensation noncompliance.

When the CSI starts linking NRs, he or she should be discussing these linkages with plant management during the weekly meetings. The CSI should also include in Block 10 of the NR that these discussions were held.

The purpose of linking NRs is to provide notification to the establishment that the further planned actions have been ineffective in, or were not implemented in a way that is, preventing the noncompliance from recurring, and that if the trend continues, the repetitive NR would support an enforcement action under the rules of practice.

The CSI should also include a statement in Block 10 of the NR stating that continued failure to meet regulatory requirements can lead to enforcement actions described in 9 CFR 500.4.

The CSI should continue to link NRs together that derive from the same or a related cause until he or she determines that an enforcement action is necessary to bring the establishment into compliance with the regulations. When the determination is made by the CSI that enforcement action is necessary, he or she should contact the DO and ask the DO to issue an NOIE to the establishment, as described in 9 CFR 500.4. The CSI should always keep his or her supervisor apprised of the situation.

NOTE: It is important to note that noncompliance with SPS requirements can be linked to Sanitation SOP or HACCP noncompliance if the cause of the noncompliance is the same. It is inappropriate for the CSI to have several NRs documenting noncompliance without linkage and then determine there is a trend occurring and list all of the individual NRs to serve as linkage. The NRs should be linked as they are issued, and the concern communicated to the establishment at the weekly meetings.

The CSI should use good judgment in making the determination which NRs to link together. For example:

- If the CSI observes condensation on an overhead that is not contaminating product and makes the determination there is SPS noncompliance, he or she should then determine whether there is a need to link that NR to a previous NR.
- One of the decisions that the CSI needs to make when trying to reach this determination is whether the second noncompliance is an isolated incident or a trend of noncompliance developing. Some of the questions that might assist the CSI to make this decision are:

1. How much time has lapsed since the previous NR was written?
2. Was this noncompliance from the same cause as the previous NR?
3. Were the establishment's further planned actions implemented?
4. Were the establishment's further planned actions effective in reducing the frequency of these noncompliances?
5. Is the establishment continuing to implement better further planned actions?

- An establishment might have several hundred pieces of equipment that are cleaned daily prior to operation. The procedures have been implemented as per the Sanitation SOP, the monitoring of the procedures have been conducted, but there may still be a small amount of residue on a contact surface somewhere in the plant at some frequency that was not found during the establishment's monitoring. To determine whether a trend is developing, the CSI would ask:

1. Are the noncompliances occurring due to the same cause?
2. Why are the noncompliances occurring? (Negligence, ineffective method, incomplete execution by the plant, or some other reason)

NOTE: The CSI can contact the supervisor for assistance in making this decision. The in-plant inspection team can also contact the TSC for assistance, if needed.

B. What is the difference between the use of trend indicators and deciding that two NRs can be linked?

Trend indicators are used on NRs to note that the noncompliance is of a particular type. The fact that two NRs have the same trend indicator marked does not necessarily have any regulatory significance. The noncompliances that are the subject of the NRs may or may not be related. NRs are to be linked when the noncompliances are from the same cause.

CSOs

PART I -- FSIS Form 5000-8, Comprehensive Assessment of the Execution and Design of an Establishment's Food Safety Systems Report

A. What FSIS Form do CSOs complete after performing a comprehensive assessment of establishments food safety systems?

CSOs complete FSIS Form 5000-8. CSOs can find this electronic form in the Public Folders/All Public Folders/Agency Issuances/Forms/5000 Series. The CSO can access this form and save it to a disk, or can open and complete the form and save the information as a file.

CSOs are only to include the facts that they observe during the plant visit, and they are to document these facts in a manner that will allow anyone reading the report to understand the observations that were made.

B. How do CSOs complete FSIS Form 5000-8?

In the first portion of the form, CSOs are to fill in the appropriate information in the blocks provided (i.e., establishment number, dates of the establishment visit, name and address of establishment, name of CSO, district, circuit visited, and reason for visit).

In the second portion of the form, CSOs provide a summary of the data assessment they compiled prior to visiting the establishment (e.g., the type of data analyzed and a brief summary of the analysis of the data).

In the third portion of the form, CSOs provide findings and recommendations. CSOs are to include:

1. A summary of the entrance meeting
2. Specific findings about design and execution elements

NOTE: CSOs are only to record facts, not suppositions or opinions. CSOs should not include solutions to findings.

3. A recommendation such as issuance of a 30-day letter or a NOIE

NOTE: The CSOs are to document the findings in a manner that explains the basis for the recommendation.

4. A summary of the exit meetings with establishment management and with in-plant personnel (e.g., attendees, main findings, recommended actions, CSO

contact for design issues, Front-line Supervisors responsible for execution of the systems, and what resources were provided to the establishment).

C. What is the distribution of the completed form?

After CSOs complete the form, they are to e-mail it to the DM and the Front-line Supervisor. The DM will file the report in a District Public Folder.

Rules of Practice

PART I -- Enforcement Actions

A. What are the three types of enforcement actions defined in the Agency's Rules of Practice?

9 CFR 500.1 defines three types of enforcement actions. They are :

- 1. A "regulatory control action," is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product;*
- 2. A "withholding action," is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process; and*
- 3. A "suspension," is an interruption in the assignment of program employees to all or part of an establishment.*

B. Although similar, what are the differences between a withholding action and a suspension?

Withholding actions affect whether the mark of inspection may be applied, while suspensions affect whether inspection verification activities will be performed.

Both withholding and suspension actions are different from a withdrawal of a Federal grant of inspection or a refusal to grant inspection. Withdrawal actions are initiated by the FSIS Administrator according to the Department of Agriculture's Uniform Rules of Practice, a different set of procedures, found at 7 CFR Subtitle A, part 1, subpart H.

PART II -- Regulatory Control Action

A. What are the regulatory provisions for a regulatory control action?

9 CFR 500.2 lists the reasons for which FSIS may decide to take a regulatory control action. They are:

- 1. insanitary conditions or practices;*
- 2. product adulteration or misbranding;*

3. conditions that preclude FSIS from determining that product is not adulterated or not misbranded; or

4. inhumane handling or slaughtering of livestock.

B. What is the purpose of a regulatory control action?

A regulatory control action covers a wide variety of inspection procedures.

A regulatory control action is a limited focus action that is to be used to address specific problems that inspection program personnel come upon in the course of their activities.

A regulatory control action permits inspection program personnel to identify regulatory noncompliance and prevent the movement of the product involved or use of the equipment or facility involved until the noncompliance has been corrected. Inspection program personnel are not required to give the establishment prior notification that they are about to execute a regulatory control action.

C. What are some examples of regulatory control actions?

- A regulatory control action may be warranted for direct product contamination with a contaminant that does not result in a food safety hazard.
- A regulatory control action may be warranted with respect to product that is economically adulterated.
- A regulatory control action may also be warranted as a result of regulatory noncompliance even when there is no product contamination or adulteration.
- A regulatory control action should be taken when inspection program personnel are assessing sanitary conditions of the establishment prior to operation and observe product residue from the previous day's production on a contact surface.
- A regulatory control action would be warranted if inspection program personnel determine that packaged product does not meet the net weight requirements.
- Inspection program personnel could initiate a regulatory control action when there is noncompliance with the SPS regulations, if control is needed to prevent contamination of product.

NOTE: Regulatory control actions are not frequently used for HACCP regulatory noncompliance unless control is necessary to prevent shipment of contaminated or adulterated product.

D. What procedures are to be used when inspection program personnel take a regulatory control action?

After determining that a regulatory control action needs to be taken, inspection program personnel will notify, as specified in 9 CFR 500.2(b), the establishment orally or in writing of the action and the basis for it. The written notification will be a NR.

As specified in 9 CFR 500.2(c), an establishment may appeal a regulatory control action by following the procedures described in 9 CFR 306.5 and 381.35. These simple procedures direct establishments that want to appeal to bring the appeal to the next level of supervision.

PART III -- Withholding Actions and Suspensions

A. When is prior notification not necessary before taking a withholding or suspension action?

9 CFR 500.3, states that *“FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because*

- 1. The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 601;*
- 2. the establishment does not have a HACCP plan as specified in 417.2;*
- 3. the establishment does not have Sanitation SOPs as specified in 416.11-416.12;*
- 4. sanitary conditions are such that products in the establishment are or would be rendered adulterated;*
- 5. the establishment violated the terms of a regulatory control action;*
- 6. an establishment representative assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; or*
- 7. the establishment did not destroy a condemned meat or poultry carcass, or part or product thereof in accordance with part 314 or part 381, subpart L of this chapter, within three days of notification.*

NOTE: As a suspension only under 9 CFR 500.3(b), the establishment is handling or slaughtering animals inhumanely.

B. Why is prior notification not necessary?

The situations in paragraph III A necessitate prompt action to protect the public health or the safety of FSIS personnel. When this is the case, but only in such cases, a withholding action or suspension action may be taken without prior notification.

Inspection program personnel taking withholding actions without prior notification must be able to document the imminent threat to public health or to the safety of inspection program personnel that made prior notification infeasible.

NOTE: Multiple instances of economic adulteration do not justify taking a withholding action without prior notification to the establishment and the opportunity to achieve compliance.

C. When is prior notification necessary before taking a withholding action or a suspension action?

9 CFR 500.4 states that *FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because:*

- 1. The HACCP system is inadequate under 417.6 of this chapter, due to multiple or recurring noncompliances;*
- 2. The Sanitation Standard Operating Procedures have not been properly implemented or maintained as specified in 416.13 through 416.16 of this chapter;*
- 3. The establishment has not maintained sanitary conditions as prescribed in sections 416.2 – 416.6 of this chapter due to multiple or recurring noncompliances;*
- 4. The establishment did not collect and analyze samples for E. coli Biotype I, and record results in accordance with 310.25(a) or 381.94(a) of this chapter; or*
- 5. The establishment did not meet the Salmonella performance standard requirements prescribed in 310.25(b) or 381.94(b) of this chapter.*

D. What is the purpose of the prior notification?

The purpose of prior notification, with an opportunity for the establishment to respond, is to provide the establishment with due process procedures.

For paragraph C above, the determinations require that the Agency compile extensive information and analyze it with care and good judgment. This makes it reasonable to provide the establishment with this information in advance. The establishment will have an opportunity to point out any factual errors made by the Agency, identify scientific or technical disagreements, and articulate differing interpretations of regulatory requirements. All this information is useful to FSIS in determining how to proceed. The plant also has an opportunity to present corrective actions.

PART IV – NOTIFICATION

A. How is an establishment notified if FSIS decides to take a withholding action or impose a suspension?

As stated in 9 CFR 500.5(a) If FSIS takes a withholding action or imposes a suspension, the establishment will be notified orally and, as promptly as circumstances permit, in writing. The written notification will:

- a. state the effective date of the action(s),*
- b. describe the reasons for the actions(s),*
- c. identify the products or processes affected by the action(s),*
- d. provide the establishment an opportunity to present immediate and corrective action and further planned preventive action; and*
- e. advise the establishment that it may appeal the action as provided in sections 306.5 and 381.35 of this chapter*

B. How is the establishment notified when it is necessary for FSIS to provide the prior notification to the establishment that there is a basis for FSIS to withhold the marks of inspection or to suspend inspection as specified in 9 CFR 500.4?

9 CFR 500.5 (b) states: The prior notification provided for in section 500.4 of this part will:

- a. state the type of action that FSIS may take;*
- b. describe the reasons for the proposed action;*
- c. identify the products or processes affected by the proposed action;*

d. advise the establishment of its right to contact FSIS to contest the basis for the proposed action or to explain how compliance has or will be achieved; and

e. advise the establishment that it will have three business days from receipt of the written notification to respond to FSIS unless the time period is extended by FSIS.

To meet the notification requirements of 9 CFR 500.5, a DM issues an NOIE to an establishment. In addition to informing an establishment about noncompliances warranting a withholding or suspension, the NOIE provides an establishment three business days to contest the basis for the proposed enforcement action or to demonstrate how compliance has been or will be achieved. Based on discussion with the establishment, the DM may extend the three business days if he or she believes this is necessary.

NOTE: An establishment may appeal all aspects of inspection decisions, including the issuance of the NOIE. However, an appeal of the NOIE is not a separate action, and the establishment is expected to make such an appeal as part of its response to the NOIE.

C. What should a DM do when he or she receives an establishment's response to an NOIE?

The DM should assess and evaluate the establishment's response and decide whether inspection should be withheld or suspended. The DM determines whether the establishment's proposed action plan addresses the problem and, if implemented, is likely to provide an acceptable solution. The DMs should consider any decisionmaking documents as required by the appropriate regulations. Also, the DM should consider the establishment's history of implementing its operating procedures and its planned corrective and preventive actions and determine whether the establishment is likely to implement its proposed actions effectively. DMs are encouraged to contact staff members from the TSC, the Office of Public Health and Science, and the Office of Policy and Program Development for assistance in making decisions.

Upon assessing and evaluating the establishment's response, the DM may decide to accept the establishment's plan, implement the appropriate enforcement action, or defer his or her decision. The following provides the DM guidance on what procedures to follow:

1. Under what circumstances should a DM accept the establishment's response?

If the establishment responds within the specified time frame, has demonstrated that compliance has already been achieved, or provides a

description of acceptable corrective and preventive actions from which the DM can find that compliance will be achieved upon implementation, the DM can accept the response, notify the establishment of the decision, ensure that the establishment implements the corrective and preventive actions in a timely manner, and close the matter with a letter of information to the establishment.

2. Under what circumstances could a DM implement an enforcement action?

If the establishment does not respond or, based on the DM's assessment and evaluation of all pertinent information, the DM finds that compliance cannot or will not be achieved upon implementation, the DM will implement the enforcement action. In those instances involving:

- withholding actions, the DM instructs the IIC to impose the withholding action and notifies the establishment as specified in 9 CFR 500.5(a). The DM's notification must include the basis for his or her decision.
- suspension actions, the DM instructs the IIC to suspend inspection and notifies the establishment as specified in 9 CFR 500.5(a). The DM's notification must include the basis for his or her decision.

D. Under what circumstances can a DM defer an enforcement decision?

A DM may defer an enforcement decision when he or she has substantial reason to believe that the establishment's proposed corrective and preventive action are adequate to eliminate the noncompliance but lacks the substantive and supporting evidence that he or she needs to make a definite decision. For example, a plant may submit an apparently adequate proposed plan and have a good history of executing its HACCP plan, but not include sufficient documentation to enable the DM to find that the proposed plan, once executed, will prevent recurrence. In this situation, a DM may choose to defer his or her enforcement decision and allow the establishment to implement the plan until it can be determined whether the plan is effective. The DM is expected to make a decision on the adequacy of the preventive action as soon as sufficient information becomes available. The DM should not defer a decision for more than 90 days without cause. The DM is to notify the establishment in writing as to why he or she deferred a decision.

If the DM determines that the establishment's plan is adequate, the DM should close the matter with a letter of information to the establishment.

If, at any time, during a period of deferment, the establishment fails to adhere to the proposed action plan, and the DM determines that an enforcement action is warranted, the DM will instruct the IIC to either impose a withholding action or effect the suspension in accordance with 9 CFR 500.4. The DM will immediately

notify the establishment management of this decision and the basis for it in accordance with 9 CFR 500.5.

PART V -- Abeyance

A. What is an abeyance, and when is it used?

9 CFR 500.5(e) states that *FSIS may hold a suspension in abeyance and allow the establishment to operate under the conditions agreed to by FSIS and the establishment.*

B. Under what circumstances could the DM hold a suspension in abeyance?

When a DM has suspended inspection, he or she may subsequently decide to hold that suspension in abeyance as specified in 9 CFR 500.5 if:

1. the establishment presents a plan that demonstrates to the satisfaction of the DM that the establishment has designed corrective and preventive actions that are appropriate to meet the regulatory requirement; and

2. it is necessary to allow the establishment to operate after implementing these corrective and preventive actions so the DM can determine whether the establishment is able to adequately execute the plan. The DM should not hold a suspension in abeyance until the corrective and preventive actions are implemented, and the abeyance should not be for more than 90 days without cause.

If the establishment has a history of failing to meet the criteria discussed above, the DM may decide not to accept the establishment's plan.

If the DM decides to put the suspension in abeyance, and the establishment fails to either meet regulatory requirements or maintain regulatory compliance, during the abeyance period, the DM may lift the abeyance and put the suspension back in effect. If this occurs, the DM will instruct the IIC to suspend inspection in accordance with 9 CFR 500.4 and immediately notify the establishment management in accordance with 9 CFR 500.5(a). The DM will also contact the Acting Regional Investigation Manager.

FSIS DIRECTIVE

6040.1

8/26/93

DISPOSITION OF SHEEP AND THEIR CARCASSES IMPLANTED WITH ELECTRONIC IDENTIFICATION DEVICES

I. PURPOSE

This directive provides guidance to ensure that electronic identification devices implanted in sheep under the Voluntary Scrapie Flock Certification Program do not enter human or animal food channels.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

MPI Regulations, Parts 301, 309, 311, 314, and 318
FDA Regulations, 21 CFR Part 170.3
APHIS Regulations, 9 CFR Parts 54 and 74

V. ABBREVIATIONS

The following are used in their shortened form in this directive:

APHIS	Animal and Plant Health Inspection Service
EID	Electronic Identification Device
FDA	Food and Drug Administration
INAD	Investigational New Animal Drug
IO	Inspection Operations
VS	Veterinary Services, APHIS
VSFCP	Voluntary Scrapie Flock Certification Program

VI. DEFINITIONS

A. **Scrapie.** A nonfebrile, transmissible, insidious, and degenerative disease affecting the central nervous system of sheep and goats.

B. **Voluntary Scrapie Flock Certification Program.** A voluntary State/Federal/Industry Cooperative Program established and maintained to reduce the occurrence and spread of scrapie, and to identify flocks which have demonstrated freedom from signs of scrapie and freedom from exposure to scrapie over specified periods of time.

C. **Electronic Identification Device.** An electronic ear implant, required by VS, APHIS, which provides an individual identification for certain sheep in the VSFCP. This device is also known as a transponder.

D. **Sheep Implantation Site.** The subcutaneous implant on top of the auricular cartilage at the base of the sheep's ear.

VI. BACKGROUND

A. VS, APHIS, implements the VSFCP in accordance with APHIS Regulations, 9 CFR parts 54 and 74, and the Voluntary Scrapie Flock Certification Uniform Methods and Rules, referenced further in this document.

B. FDA, which has jurisdiction regarding food additives, considers EIDs to be unapproved food additives for human food or animal feed. Accordingly, the EIDs must be removed from the sheep at the time of slaughter.

C. The Federal Meat Inspection Act sets forth mandatory inspection requirements to ensure the safety, wholesomeness, and proper labeling of meat products. FSIS inspectors condemn and monitor the disposal of carcasses, edible organs and other parts thereof in accordance with MPI Regulations. Meat products cannot contain unapproved additives.

VII. POLICY

A. The Voluntary Scrapie Flock Certification Uniform Methods and Rules require EIDs as the official means of

identification. The EIDs should be implanted subcutaneously in the animal's ear. From participating flocks, all sheep 1 year or older are required to be implanted with EIDs. All sheep in the VSFCP flocks less than 1 year of age must be implanted with EIDs whenever a change of ownership occurs, except those sheep moving within slaughter channels.

B. When sheep implanted with EIDs are presented for slaughter, the sheep must be accompanied by an INAD permit number and authorization from the Residue Operations Staff, IO, as set forth in MPI Regulations 309.17 and FDA Regulations, 21 CFR Part 511.1(a)(5), except under the conditions described in Paragraph VII. C. below.

C. Sheep that are implanted with EIDs and that are not accompanied by an INAD number and authorization may be presented for slaughter provided:

1. The sheep are from a flock that is participating in the VSFCP.

2. The sheep are marked, tagged, or otherwise identified by the owner, shipper, or establishment so that the sheep are easily recognized by the FSIS inspector from ante-mortem inspection through disposition of carcasses.

3. The sheep's ears implanted with EIDs do not enter human or animal food chains and are disposed of in accordance with requirements of the particular State or municipal authorities.

VIII. RESPONSIBILITIES

A. Establishment should:

1. Ensure that sheep are identified when notified that VSFCP sheep are presented for slaughter.

2. Ensure that the identity of the sheep implanted with EIDs is maintained from ante-mortem inspection through disposition of carcasses.

3. Ensure that the ears containing the EIDs do not enter human or animal food channels.

B. FSIS inspector will:

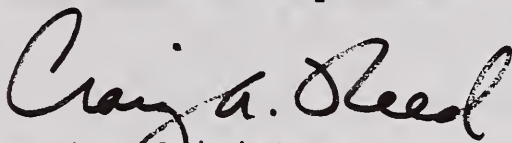
1. Monitor the establishment's identification of VSFCP sheep presented for slaughter.

2. Monitor the establishment's ability to maintain the identity of sheep implanted with EIDs from ante-mortem inspection through disposition of carcasses.

3. Monitor the establishment's ability to prevent ears containing the EIDs from entering human or animal food channels.

IX. FURTHER GUIDANCE

Any questions regarding this directive should be referred to the next level of supervision.



Deputy Administrator
Inspection Operations

☆U.S. Government Printing Office : 1993 - 341-280/81388



United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C.
20250

OFFICIAL BUSINESS
Penalty for Private Use, \$300

FIRST CLASS MAIL

37/446MPSLD1594 R1 103-0001
E1
US DEPT OF AGRICULTURE
FOOD & NUTRI INFORMATION CNTR
NAT'L AGRI LIBRARY, RM 304
BELTSVILLE MD 20705-2351

FSIS DIRECTIVE

6210.1
Rev. 1

9/24/93

POST-MORTEM DISPOSITION OF POULTRY

I. PURPOSE

The purpose of this directive is threefold:

A. To clarify the difference between the disposition of carcasses missing all of the viscera and carcasses missing part of the viscera;

B. To eliminate the procedure of "pooling" viscera in poultry; and

C. To provide post-mortem disposition guidelines.

II. CANCELLATION

FSIS Directive 6210.1, dated 2-4-87.

III. REFERENCE

MPI Regulation 381.76(a).

IV. REASON FOR REISSUANCE

This directive has been reorganized and rewritten to clarify FSIS policy on the post-mortem disposition of poultry carcasses missing all or part of the viscera.

V. POLICY

A. A uniform policy must be followed in poultry slaughter establishments for the disposition of carcasses with part or all of the viscera missing. MPI Regulation 381.76(a) states that "...No viscera or any part thereof shall be removed from any poultry processed in any official establishment, except at the time of post-mortem inspection, unless their identity with the rest of the carcass is maintained in a manner satisfactory to the inspector until such inspection is made."

DISTRIBUTION: Inspection Offices, T/A Inspectors, OPI: IO/SOS
Plant Mgt., T/A Plant Mgt., TRA, ABB, PRD, AID

B. A clear distinction must be made between carcasses categorized as having "no viscera" and those "missing part of the viscera." Absence of such a distinction has contributed to a lack of uniform disposition nationwide. This lack of uniform disposition has been magnified by the implementation of the Streamlined Inspection System (SIS), New Line Speed (NELS) Inspection System, and the New Turkey Inspection (NTI) System, since these systems use the category "no viscera" as an error in the presentation log.

VI. CATEGORIZING CARCASSES MISSING ALL OR PART OF THE VISCERA

A. Carcasses are to be classified as having "no viscera" if:

1. No visceral parts are present; or
2. Some visceral parts are present, but all **three "major organs" (heart, liver, spleen)** are missing.

B. Carcasses are to be classified as "missing part of the viscera" if some visceral parts are present, including at least one major organ.

NOTE: For purposes of this classification, one-half or more of the liver will be considered the same as a whole liver.

VII. POOLING VISCERA

The procedure for pooling viscera separated from carcasses prior to inspection is neither practical nor easy to control sufficiently to ensure adequate inspection, especially in the new poultry inspection systems and, therefore, is no longer allowed.

VIII. POST-MORTEM DISPOSITION

A. A veterinary inspector-in-charge (IIC) is responsible for disposition accuracy. Under veterinary supervision, inspectors may condemn poultry carcasses, parts, or organs obviously unwholesome or unfit for human food. Any carcass showing signs of an abnormal physiological state but not obviously condemnable shall be retained for the veterinary medical officer, who shall make a judgment on the disposition as required by regulations.

B. Condemnations are to be recorded on FSIS Form 6000-16, Poultry Inspection - Lot Tally Sheet.

C. The disposition guidelines are as follows:

1. For a carcass(es) classified as "missing part of the viscera," the inspector shall:

- a. pass the carcass(es) as wholesome;
- b. retain the questionable carcass(es) and/or viscera for veterinary disposition; or
- c. condemn the carcass(es) per disease condition.

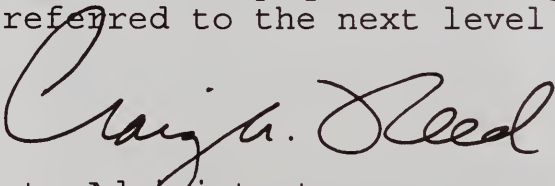
2. For carcass(es) classified as having "no viscera," the inspector shall hang back the carcass(es) for veterinary disposition until the IIC can:

- a. determine if the entire lot of "no viscera" carcass(es) should be retained due to the existence of pathological/unwholesome conditions; or
- b. direct the on-line inspectors to pass carcasses in that lot, if pathological/unwholesome conditions do not exist.

D. The inspector's helper may assist the inspector in post-mortem inspection by:

1. Removing carcasses from the line;
2. Marking the FSIS Form 6000-16;
3. Identifying carcasses; and
4. Trimming defects and abnormalities (when time permits as specified in nontraditional inspection systems).

If there are any questions regarding this directive, they should be referred to the next level of supervision.



Deputy Administrator
Inspection Operations

United States Department of Agriculture

Food Safety and Inspection Service

**Washington, D.C.
20250**

**OFFICIAL BUSINESS
Penalty for Private Use, \$300**

FIRST CLASS MAIL

FSIS DIRECTIVE

2003 FEB - 2 6210.2

12-19-2002

INSPECTION OF POULTRY FEET

I. PURPOSE

This directive provides instructions to inspection program personnel for performing inspection activities on poultry feet and to help them decide whether the poultry feet are eligible to receive the United States Department of Agriculture (USDA) mark of inspection.

II. CANCELLATIONS

FSIS Notice 59-01, Inspection of Poultry Feet (Paws) dated December 21, 2001

III. [Reserved]

IV. REFERENCES

9 CFR 381.79

V. BACKGROUND

Poultry feet qualify to receive the USDA mark of inspection when their identity is maintained with the carcass through the post-mortem carcass inspection process, and they are found to be not adulterated. Poultry carcasses or feet passed for human food may, in accordance with 9 CFR 381.79, receive the mark of inspection based on an examination of the feet as well as the carcass as a whole.

VI. METHODS FOR PRODUCING FEET ELIGIBLE FOR THE MARK OF INSPECTION

A. Under Inspection System Procedure (ISP) activity code 04C01, inspection program personnel will verify that establishments desiring to produce poultry feet that are eligible to bear the mark of inspection maintain the identity of the feet with the rest of the carcass from which they were derived for post-mortem inspection and disposition purposes by employing one of the following methods:

DISTRIBUTION: Inspection Offices; T/A
Inspectors; Plant Mgt; T/A Plant Mgt;
TRA; ABB; TSC; Import Offices

OPI: OPPD

1. Expose the hock joints, leaving the feet attached to the carcass by a tendon or skin part, provided:

a. the feet do not obstruct the view of the carcass in such a way as to hinder the inspector's ability to perform the established post-mortem inspection procedure.

b. sanitary conditions are maintained.

2. Process detached poultry feet by a **batch method** that ensures that when a single carcass is condemned on postmortem, the correlative batch of feet collected in a separate location is condemned, provided:

a. the batch method procedure to be used is acceptable to the Inspector-in-Charge (IIC). (**NOTE:** Establishments may perform identification and disposition of carcasses affected with systemic conditions before the carcass/feet separation. Such an approach is to be set out in the batch procedure description. Carcasses disposed of by establishment personnel are reported as plant rejects); and

b. the procedure ensures that whenever inspection program personnel condemn a carcass at any post-mortem inspection station, the establishment helper immediately communicates the condemnation to management. In response, management disposes of the batch of poultry feet containing the feet from the condemned carcass.

VII. POST-MORTEM INSPECTION PROCEDURES FOR POULTRY FEET

A. Inspection program personnel are to condemn carcasses, including the feet, that exhibit signs of systemic conditions that may render the carcass and its parts adulterated, e.g. septicemia/toxemia or leukosis complex or localized conditions with evidence of general systemic involvement e.g. inflammatory process (IP) with general systemic disturbance.

B. Inspection program personnel are to pass carcasses, including the feet, with certain defects not requiring condemnation of the entire carcass (localized defects), e.g. localized airsacculitis or bruises. Under any of the regulatory poultry slaughter systems (SIS, NELs, and NTI) except the Traditional Inspection System, localized defects are removed by establishment personnel subject to FSIS verification checks.

VIII. INSPECTION PROGRAM PERSONNEL VERIFICATION RESPONSIBILITIES

Inspection program personnel will examine a random sample of processed or packed feet and verify that the product is wholesome and not adulterated, and that it can bear the mark of inspection. In addition, in establishments choosing to use a batching system, they verify that the establishment is following their batch method procedures. They will also verify that establishments:

A. are maintaining sanitary conditions at all times during feet processing, chilling, and packaging;

B. have considered whether there are any food safety hazards that are reasonably likely to occur in the production of feet eligible for the mark of inspection as part of their hazard analysis (see 9 CFR 417.2); and

C. have a procedure in place to ensure that feet with localized or processing defects that could render the feet adulterated are removed prior to packing. Localized defects include sores, compound fractures, and bruises. Processing defects include extraneous material (specks, smears, attached or unattached cuticle, or toenail) and mutilation (mutilation to the skin or muscle). (NOTE: Localized and processing defects generally are not food safety hazards).

IX. FURTHER GUIDANCE

For technical guidance contact the Technical Service Center. For guidance related to regulatory activities refer questions through supervisory channels.



Deputy Administrator
Office of Policy and Program
Development

**United States Department of Agriculture
Food Safety and Inspection Service
5601 Sunnyside Avenue, Mail Drop 5241
Beltsville, MD 20705-5241**

**OFFICIAL BUSINESS
Penalty for Private Use, \$300**

**FIRST-CLASS MAIL
POSTAGE & FEES PAID
USDA-FSIS
Permit No. G-42**

FSIS DIRECTIVE

6550.1

12-9-93

LINE SPEEDS FOR HEAVY YOUNG CHICKENS (BROILERS, ROASTERS)

I. PURPOSE

This directive sets forth recommended maximum line speeds for official establishments that process heavy young chickens under the Streamlined Inspection System and the New Line Speed Inspection System.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

MPI Regulations, Sections 381.76 and 381.170

V. ABBREVIATIONS

The following will appear in their abbreviated form in this directive:

IIC	Inspector in Charge
MPI	Meat and Poultry Inspection
NELS	New Line Speed Inspection System
SIS	Streamlined Inspection System
SIS-1	Streamlined Inspection System with one inspector
SIS-2	Streamlined Inspection System with two inspectors

VI. BACKGROUND

A. Section 381.76 of the MPI regulations prescribes maximum line speeds for young chickens processed under SIS and NELS. SIS may be performed by one inspector or two inspectors. The maximum line speed is 35 birds per minute under SIS-1 and 70 birds per minute under SIS-2. The maximum line speed for NELS is 91 birds per minute.

B. During the development of SIS and NELS in the 1980's, FSIS conducted studies to determine procedures and line speeds for those systems. At that time, young chickens weighed less

than 6 pounds and had only a small amount of fat on the abdominal flap. Consequently, an inspector uses only one hand to manipulate the abdominal flap to view the inside cavity of these birds. The maximum line speeds prescribed in Section 381.76 of the MPI Regulations are based on data gathered during studies using broilers weighing 6 pounds or less.

C. A significant number of young chickens being processed today weigh over 6 pounds. Heavy young chickens tend to have more fat than the smaller birds, requiring inspectors to use both hands to manipulate the fatter abdominal flaps for viewing the inside cavities of the birds.

VII. LINE SPEED GUIDELINES--ADJUSTMENTS FOR HEAVY YOUNG CHICKENS

A. Line speeds must be adjusted as necessary to allow for proper inspection of heavy young chickens. It is recommended that the following line speeds not be exceeded to permit adequate inspection of heavy young chickens processed under SIS and NELS:

Recommended Line Speeds for Heavy Young Chickens

SIS-1	31 birds per minute
SIS-2	55 birds per minute
NELS	73 birds per minute

B. In each case, the actual line speed may be less. The line speed must not exceed that which permits adequate examination of each carcass or part. Actual line speeds will vary, depending on a variety of conditions.

VIII. RESPONSIBILITIES

A. IIC:

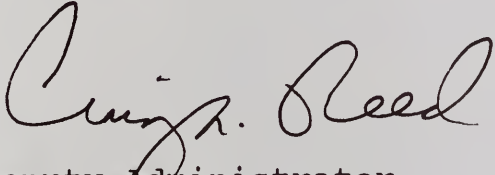
1. Ensure that weights of heavy young chickens are determined as necessary by randomly selecting and weighing 10 birds per lot at the establishment's transfer station. Weighing may be done by the establishment or inspection personnel.

2. Ensure that the line speed is adjusted as necessary to allow for proper inspection of heavy young chickens. If the average weight of the 10 young chickens exceeds 6 pounds, the lot is defined as heavy young chickens.

B. Establishment:

1. Provide scales for random weighing at a location acceptable to the IIC.
2. Conduct random weighing of young chickens in a manner acceptable to the IIC.
3. Adjust line speeds as directed by the IIC.

Any questions regarding this directive should be referred to the next level of supervision.

A handwritten signature in cursive script, reading "Craig H. Reed". The signature is written in dark ink and is positioned above the printed title.

Deputy Administrator
Inspection Operations

United States Department of Agriculture

Food Safety and Inspection Service

**Washington, D.C.
20250**

**OFFICIAL BUSINESS
Penalty for Private Use, \$300**

FIRST CLASS MAIL

0151975
U538

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

6700.1

11/27/2002

RETAINED WATER IN RAW MEAT AND POULTRY PRODUCTS

I. PURPOSE

This Directive provides instructions to inspection program personnel on the procedures for conducting inspection activities concerning the consumer protection standards for retained water in raw meat and poultry products. **(NOTE: THIS DIRECTIVE IS NOT EFFECTIVE UNTIL JANUARY 9, 2003).**

II. [Reserved]

III. [Reserved]

IV. REFERENCES

9 CFR Section 441.10

V. BACKGROUND

A. Raw, single-ingredient meat and poultry products that retain water as the result of post-evisceration processing in excess of naturally occurring moisture are subject to the retained water regulations. Section 9 CFR 441.10, which becomes effective January 9, 2003, allows for retained water in raw livestock and poultry carcasses and parts only to the extent that it is an unavoidable consequence of a process used to meet applicable food safety requirements. The amount of water retained in the product in excess of naturally occurring moisture must be prominently declared on the label. Any establishment that uses a post-evisceration process that results in water retention in a raw livestock or poultry carcass or part must maintain on file a written data-collection protocol in accordance with 9 CFR 441.10 (c)(1). Establishments' protocols and procedures are to be available to FSIS. An establishment does not have to maintain a protocol on file if it has data or information that clearly demonstrate that its products do not retain water as a result of the process, e.g. spraying boneless meat with antimicrobials where the end product does not retain water from the antimicrobial application process.

DISTRIBUTION: Inspection Offices; T/A Inspectors;
Plant Mgt; T/A Plant Mgt; TRA; ABB; TSC; Import Offices

OPI: OPPD

B. Establishments may include a no-retained-water statement on the label when product has not been exposed to a post-evisceration process that adds water, or the establishment has data or information that establishes that the process does not add water to the product.

C. FSIS does not require official establishments to use any specific method to make a retained water determination. The method chosen in calculating water absorption and retention, however, should be reproducible and verifiable. For example, an establishment may use physical water pick-up tests, weighing carcasses post-evisceration, before the use of water directly contacting product, and again just prior to final packaging and labeling. Likewise, an establishment may develop its protocol based on laboratory analysis for naturally occurring and total water content of carcasses before and after the application of water for food safety purposes.

D. In-plant inspection program personnel who have questions about the validity of the method being used by an establishment should consult the Technical Service Center (TSC).

VI. POST-EVISCERATION PROCESS

A. The following are examples of post evisceration processes involving the use of water that would subject products to the requirements of 9 CFR 441.10 (Retained Water):

1. Post-evisceration washing of livestock and poultry carcasses with hot water, cold water, or an antimicrobial, including on-line reprocessing systems.
2. Livestock carcass spray chilling with or without an antimicrobial.
3. Water or ice chilling of poultry carcasses or giblets with or without an antimicrobial.
4. Water or ice chilling with or without an antimicrobial used to remove heat from parts: hearts, kidneys, livers, tongues, cheeks, salivary glands, spleens, pancreases, ears, tails, or head meat trimmings, including head meat, cheek meat, or tongue meat.
5. Post chill spraying of meat and poultry carcasses or parts, with water or an antimicrobial solution.
6. Spraying byproducts (e.g. hearts, livers, tongues, cheeks, salivary glands, spleens, pancreases, chitterlings, stomachs, ears, and tails) with an antimicrobial after they have been converted from their natural state to an edible state (e.g., after the lining has been removed from tripe, and the tripe has been cleaned).

7. Spraying bones with an antimicrobial used for advanced meat recovery systems or for mechanical deboning.

8. Spraying meat trimmings, including head meat, cheek meat, or tongue meat, with an antimicrobial solution.

B. The following are examples of post evisceration processes involving the use of water that would not subject products to 9 CFR 441.10.

1. Flushing stomachs, small intestines, large intestines, rectum, braided marrow gut, and chitterlings to remove digestive tract contents.

2. Scalding of pork stomachs, pork tongues, and beef lips, intestines, and stomachs.

3. Flushing the gizzard with water to remove digestive tract contents.

4. Washing with water to remove excess blood, e.g. washing hearts, livers, brains, and tendons.

5. Washing beef heads with water.

Note: On a case-by-case basis, the Inspector-in-Charge (IIC), in consultation with his or her supervisor and the TSC, will evaluate other post evisceration processes involving the use of water to determine whether the resulting products are subject to 9 CFR 441.10.

VII. VERIFICATION PROCEDURES

A. When directed by PBIS-generated procedure 04B04, the IIC will verify the establishment's compliance with the other consumer protection (OCP) requirements of 9 CFR 441.10 by reviewing and analyzing the establishment's data and by observing the processes carried out by the establishment. The IIC will:

1. verify that the establishment has on file and available to FSIS its written data-collection protocol (9 CFR 441.10(c)(1)) or data that demonstrate that the process does not result in retained water in excess of naturally occurring moisture; and

2. review all changes or revisions to an existing protocol. An IIC should inform an establishment that it should notify him or her whenever it has a new protocol, has made changes to an existing protocol, or has changed its processing procedures in a manner that would require a new or revised protocol.

Note: Establishments that develop new protocols or revise existing protocols should submit the new or revised protocol to FSIS for review by the Technology Program Development Staff (TPDS) of the Office of Policy and Program Development (OPPD):

by mail to: USDA/FSIS/OPPD/TPDS
1400 Independence Ave., SW
Room 405
Cotton Annex
Washington, DC 20250;
or by fax to: (202) 205-0080;
or by e-mail to: tpds.protocols@usda.gov

9 CFR 441.10(d) lists the elements to be included in the protocol. FSIS will notify establishments of the outcome of the review in no more than 30 days after the Agency receives the protocol with either a no-objection letter, or a letter listing the Agency's objections to the submitted protocol. Establishments may choose to implement a new or revised protocol and use a label reflecting the new percentage water gain before receiving FSIS notification of the review outcome. If the FSIS protocol review identified objections or requires changes to the submitted protocol, the establishment will be expected to modify the protocol, and if necessary, the retained water statement.

3. Verify that the establishment is following its protocol, and that the protocol reflects the actual processing system in use.

4. Calculate the total retained water in the product using establishment data to verify that the percent retained water declared on the label is supported by the data generated by the protocol. The percent retained water should be within the sampling variability or the allowed labeling variation. That is, continuing measurements of actual retained water demonstrate that it is within 20 percent of the declared retained water level for the product.

B. Inspection program personnel are to document non-compliances on a Non-Compliance Record (NR), FSIS Form 5400-4, if:

1. the establishment has a product covered by 9 CFR 441.10 without a protocol or data or information that clearly demonstrate that the product does not retain water as a result of a given process;

2. the establishment is not following the written protocol;

3. the retained water declared on the label is less than the level actually retained in the product as determined using the protocol, considering the allowable and appropriate variation; or

4. the establishment records are incomplete and do not allow for the verification of the accuracy of the retained water label declaration.

Note: IICs who, based on observation or data analysis and actual calculations, have reason to believe that an establishment may be systematically adulterating or misbranding its products should submit their information through supervisory channels to the district office. The District Manager will determine the course of action to take.)

VIII. LABELING REQUIREMENTS

A. Inspection program personnel are to verify that the labeling of raw single-ingredient products accurately declares any water retained by carcasses or parts of carcasses resulting from post-evisceration processing that was done to meet applicable food safety requirements. Carcasses or parts of carcasses may be whole, cut-up, or ground. Refer to attachment 1 and 2 for additional labeling questions and answers and examples of products. Some labeling principles are:

1. Any water retained besides naturally occurring moisture in such products must be reflected in a prominent statement on the principal display panel of the product label, e.g., up to X percent retained water, or may contain up to X percent absorbed water.

2. The generic labeling regulations 9 CFR 317.5 and 9 CFR 381.133 and the nutrition labeling regulations in Part 317 Subpart B and Part 381 Subpart N apply to retained water products as they apply to other single-ingredient products.

3. The permitted labeling variation is 20 percent from the declared amount within the retained water statement.

B. Multi-ingredient product labeling is not affected by retained water in a meat or poultry component. Thus, retained water is not an ingredient, and the retained water statement on meat or poultry components is not an ingredient declaration. Refer to attachment 2 for multi-ingredient product examples.

1. Any retained water in raw meat or poultry items used as ingredients would not be declared on the labeling of multi-ingredient products, e.g., raw or cooked sausage, pre-basted turkeys, or deli meats.

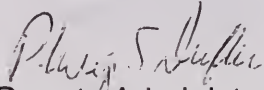
2. Retained water has no effect on the declared amount of flavor solution in basted, marinated, injected, tumbled, etc. products.

3. Standards of identity or composition are not affected by the retained water rule.

IX. IMPORT PRODUCT

Import raw single ingredient meat and poultry products that bear an X percent retained water statement, or a statement declaring no retained water, may be sampled periodically during port-of-entry reinspection to verify labeling claims. Exporting country

inspection systems are responsible for performing functions equivalent to those set forth in this Directive and for certifying that products for export to the United States meet FSIS import requirements. FSIS will verify the equivalence of exporting country water retention regulatory programs during annual on-site audits.



Deputy Administrator
Office of Policy and Program Development

Additional Labeling Questions and Answers

1. If a plant determines through testing that the amount of retained moisture in a particular item is a fractional percentage (e.g., 0.3, 0.4, 0.5, or 1.3 percent, etc.), how would the agency expect this to be labeled?

Answer: As with nutritional labeling, rounding rules would apply (i.e., round to the nearest whole number). Therefore, labeling of fractional percentages of retained water would not be required. For example, 0.5 percent-retained water is rounded up to 1 percent and 1.3 percent is rounded down to 1 percent.

2. Are labeling statements permitted explaining the purpose of the retained water, e.g., “for safety purposes contains up to X percent retained water?”

Answer: Explanatory statements regarding the retained water will be reviewed by the Labeling and Consumer Protection Staff on a case-by-case basis since they are viewed as special claims. The statements will be evaluated to determine whether they misrepresent products or imply that products are safer than other similarly chilled products.

3. Is there a size requirement for the prominent lettering in the retained-water statement?

Answer: There is no letter size requirement for the percent-retained-water statement, but if the lettering is inconspicuous or not visible to consumers with normal visual acuity, it is not prominent. Prominence is determined by several factors, including size of lettering in the statement compared with other lettering on the label, location of the statement, and color contrast between the lettering and the background.

4. Can the term “moisture” be used instead of the term “water” within the retained water statement?

Answer: The term “moisture” is not acceptable since it does not convey the specific substance used during the post-evisceration chilling of the product.

5. Is the retained water statement required on a shipping container label when the product inside is packaged and labeled?

Answer: The shipping container is not required to bear a retained water statement since the regulation addressing the labeling of retained water products applies to the principal display panel of immediate containers. Shipping containers holding packaged and labeled products do not have principal display panels.

6. Most meat carcasses, half carcasses, and primals are shipped from the establishment with only the mark of inspection identifying them. If the carcass gains water as a result of the chilling process, a water retention statement is required. How could an establishment meet this requirement if it is shipping full and half carcasses and primals to other establishments for further processing into retail cuts, ground beef, etc?

Answer: Retained water in red meat carcasses, half carcasses, quarters, primals, or byproducts that are simply branded with a mark of inspection would also need to be declared with a prominent retained water statement. This could be accomplished by adding the retained water statement by branding or affixing with a secure tag.

7. Can pressure sensitive stickers be used to modify the percent-retained water statement and is handwriting permitted for the value of the retained water?

Answer: Pressure sensitive stickers may be applied to labeling to modify the percent-retained water statement. This type of change is a generic approval. Handwriting is not permitted for the value of the retained water because a legibility factor involved with handwriting. The value should be uniform and produced by mechanical means as with other mandatory features.

8. The label contains a "no retained water" claim. Does the 20 percent variation apply?

Answer: The 20 percent variation permitted for the retained water statement would not apply when a no retained water claim is made on labeling. Rounding rules apply. Thus, the product could not retain more than 0.49 percent water such that the rounded amount of water is 0 percent.

9. How does retained water affect restricted ingredients, e.g., bacon?

Answer: The levels for restricted ingredients remain the same as indicated in the substance chart, 9 CFR 424.21(c), e.g., sodium nitrite and sodium erythorbate are based on the weight of the meat or poultry product regardless of the amount of water possibly retained in the meat or poultry as a result of post-evisceration processing.

10. Does the regulation cover products that may be treated with water which produces no gain in net weight of the finished product?

Answer: The regulation, including its requirement of the submission of protocols, deals with products for which the manufacturer anticipates a particular moisture-based weight gain, is targeting its procedures to control that gain, and will label its products accordingly. As a result, establishments that anticipate zero weight gain are not required to develop and submit protocols. Such establishments should, however, maintain records that demonstrate through data or information that their product does not gain water as a result of the process.

11. Does the regulation apply to intermediate (in-process) processing steps?

Answer: No. The regulation focuses on the labeling of single-ingredient finished products as they leave the establishment. Procedures, such as the application of antimicrobial solutions or of water that may temporarily contribute weight to the product, need not be declared. However, establishments are expected to maintain data clearly demonstrating that the finished products do not retain water.

12. Is it acceptable to export products with retained water without labeling bearing a percentage retained water statement?

Answer: Deviations from domestic labeling rules are permitted in accordance with 9 CFR 317.7 or 381.128. However, the labeling record should contain documentation in the form of a letter that is required from an official with the foreign government or the importer in the country to which the product is destined. The letter would specify that country's laws that would permit the deviations.

13. Can one letter be applied to multiple products for export?

Answer: Yes, if the letter is complete by indicating all exported products with labeling deviations and is only for the country to which the products are destined.

14. Does the retained water rule apply to ice-glazed poultry?

Answer: Yes. A retained water statement is required because the product is single ingredient regardless of whether the product is ice-glazed or not. The ice-glaze is not an ingredient; its purpose is to prevent shrinkage during freezing.

15. How are single-ingredient products with retained water (e.g., bearing contains X percent retained water statements) handled when they are sent in bulk to retail stores for packaging? What effect would in-store cut-up or grinding operations have on the labeling of single-ingredient products with retained water at the retail store?

Answer: The retained water statement that is applied to the cuts or ground products would be the same as the retained water statement that was applied to the bulk product. However, the retail store may choose to show through documentation that less or no water is retained in the cuts or ground product and to label the product accordingly.

16. What happens to a product when the retained water declaration exceeds the 20 percent label declaration?

Answer: The company has two options. One is to accurately relabel the product. The other option would be to allow the product to drain so that the retained water statement is truthful. This may involve re-packaging the product unless the product is ice pack poultry in drainable containers.

17. How is the retained water statement handled with chitterlings since the product is allowed to be packaged with up to a 20 percent purge?

Answer: Many years ago, before 1992, FSIS allowed, under normal conditions and good manufacturing practices, purge in containers of chitterlings not to exceed 20 percent of the marked weight of the product. The policy is long-held and is practiced industry wide. Consumers who purchase this product are aware of the policy and practice and have come to expect moisture content in chitterlings. As a result of this long-standing policy, no retained water statement is required when chitterlings are packaged with a purge. If chitterlings retain water during post evisceration processing and are not packaged with a purge, the product's labeling is required to bear a retained water statement.

18. What is FSIS position regarding the use of water in thawing process?

Answer: Frozen meat, meat byproducts, poultry, or poultry byproducts are often thawed using chilled water. Establishments have to assess whether the product is absorbing water during the thawing process. If the final product is raw, single-ingredient, and absorbed water during the thawing process, a retained water statement is necessary. However, if the final product is subsequently processed into a multi-ingredient item or cooked, the retained water is not a labeling or standards concern.

Product Examples

Example 1

Basted turkey injected with up to 3 percent flavor solution is made with turkey containing 3 percent absorbed water. The ingredient declaration would not identify any retained water in the turkey that would have possibly been absorbed during post evisceration processing in the slaughter establishment because the retained water is not an ingredient. The retained water in the turkey would not affect the 3 percent flavor solution injected into the product and declared as part of the product name.

Example 2

Beef and Turkey Italian Sausage contains starting material that is labeled as “turkey containing 3 percent retained water.” The ingredient declaration would not identify the retained water in the turkey because the retained water is not an ingredient. The post evisceration retained water in the turkey would not affect the 3 percent added water limit for the finished product that is established by the standard of identity or composition. Water added to facilitate mixing to dissolve ingredients is an ingredient and is permitted up to 3 percent in raw sausage.

Example 3:

When beef trimmings that have been sprayed with chilled water so that they contain 5 percent retained water are used to make a single ingredient raw ground product, like ground beef or hamburger, the resulting product must be labeled to declare any retained water above naturally occurring water. Also, single-ingredient ground poultry produced from poultry containing retained water would be required to be labeled to declare any retained water above naturally occurring water. The retained water would not affect compliance with the standard, i.e., no added water, because retained water is not an ingredient. If the products were subsequently cooked, the retained water would have no effect on the finished product or its labeling.

**United States Department of Agriculture
Food Safety and Inspection Service
5601 Sunnyside Avenue, Mail Drop 5241
Beltsville, MD 20705-5241**

**OFFICIAL BUSINESS
Penalty for Private Use, \$300**

**FIRST-CLASS MAIL
POSTAGE & FEES PAID
USDA-FSIS
Permit No. G-42**

TS1975
1538

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

USDA
NATHAN I. ROSEN LIBRARY
2005 NOV 30 P 3:20

FSIS DIRECTIVE

6900.2

Humane Handling and Slaughter of Livestock

PART I -- General

I. Purpose

This directive informs inspection program personnel of the requirements, verification activities, and enforcement actions for ensuring that the handling and slaughter of livestock, including the slaughter of livestock by religious ritual methods, is humane. This directive explains how inspection program personnel should approach these activities.

II. [Reserved]

III. [Reserved]

IV. References

9 CFR parts 313 and 500, the Humane Methods of Slaughter Act - 7 U.S.C. 1901, 1902, and 1906, and FSIS Directive 6900.1 – Humane Handling of Disabled Livestock.

V. Background

A. The Humane Methods of Slaughter Act of 1978 (HMSA) (Section 1901, 1902 and 1906, Attachment 1) states that the slaughtering and handling of livestock are to be carried out only by humane methods. In that Act, Congress determined (among other things) that the use of humane methods of handling and slaughtering livestock prevents needless suffering of animals and results in safer and better working conditions for employees in slaughter establishments.

B. Once a vehicle carrying livestock enters an official slaughter establishment's premises, the vehicle is considered to be a part of that establishment's premises. The animals within that vehicle are to be handled in accordance with 313.2.

PART II -- Verification of the Livestock Pens, Driveways and Ramps

A. What are the regulations related to livestock pens, driveways and ramps?

Section 313.1 states:

(a) Livestock pens, driveways and ramps shall be maintained in good repair. They shall be free from sharp or protruding objects which may, in the opinion of the inspector, cause injury or pain to the animals. Loose boards, splintered or broken planking and unnecessary openings where the head, feet, or legs of an animal may be injured shall be repaired.

(b) Floors of livestock pens, ramps, and driveways shall be constructed and maintained so as to provide good footing for livestock. Slip resistant or waffled floor surfaces, cleated ramps and the use of sand, as appropriate, during winter months are examples of acceptable construction and maintenance.

(d) Livestock pens and driveways shall be so arranged that sharp corners and direction reversal of driven animals are minimized.

NOTE: Verification of compliance with 9 CFR 313.1(c) is addressed in FSIS Directive 6900.1, Humane Handling of Disabled Livestock.

B. How do inspection program personnel verify compliance with this regulation?

When verifying compliance with 9 CFR 313.1(a), (b), and (d), inspection program personnel should determine whether the pens, driveways, and ramps are designed and maintained to prevent injury or pain to the animals. To do this, inspection program personnel need to seek answers to questions such as:

1. Are pens free of loose boards or openings, so that the head, feet or legs of an animal will not be injured?
2. Are the floors of pens, ramps, and driveways constructed so that an animal is not likely to fall (e.g., cleated, waffled, use of sand)?
3. Are driveways arranged so that sharp turns or sudden reversals of direction are minimized, so that they are not likely to cause injury to the animals?

These questions are examples and are not an all-inclusive list.

C. What actions do inspection program personnel take if there is a noncompliance with 9 CFR 313.1?

If inspection program personnel observe a noncompliance with 9 CFR 313.1, they are to determine whether the situation does or will immediately lead to animal injury or inhumane treatment. If the noncompliance is such that it will not immediately lead to injury (e.g., a few loose boards), inspection program personnel are to take action as set out in Part VI A. If the noncompliance is such that an animal has been injured (e.g., an animal's leg falls in between boards), inspection program personnel are to take action as set out in Part VI B.

PART III – Verification of Humane Handling of Livestock

A. What is the regulation related to handling of livestock?

Section 313.2 states:

(a) Driving of livestock from the unloading ramps to the holding pens and from the holding pens to the stunning area shall be done with a minimum of excitement and discomfort to the animals. Livestock shall not be forced to move faster than a normal walking speed.

(b) Electric prods, canvas slappers, or other implements employed to drive animals shall be used as little as possible in order to minimize excitement and injury. Any use of such implements which, in the opinion of the inspector, is excessive, is prohibited. Electrical prods attached to AC house current shall be reduced by a transformer to the lowest effective voltage not to exceed 50 volts AC.

(c) Pipes, sharp or pointed objects, and other items which, in the opinion of the inspector, would cause injury or unnecessary pain to the animal shall not be used to drive livestock.

(d) Disabled livestock and other animals unable to move. (Also refer to FSIS Directive 6900.1, Humane Handling of Disabled Livestock).

(1) Disabled animals and other animals unable to move shall be separated from normal ambulatory animals and placed in the covered pen provided for in section 313.1(c).

(2) The dragging of disabled animals and other animals unable to move, while conscious, is prohibited. Stunned animals may, however, be dragged.

(3) Disabled animals and other animals unable to move may be moved, while conscious, on equipment suitable for such purposes; e.g., stone boats.

(e) Animals shall have access to water in all holding pens and, if held longer than 24 hours, access to feed. There shall be sufficient room in the holding pen for animals held overnight to lie down.

(f) Stunning methods approved in section 313.30 shall be effectively applied to animals prior to their being shackled, hoisted, thrown, cast or cut.

B. How do inspection program personnel verify compliance with these regulations?

When verifying compliance with 9 CFR 313.2, inspection program personnel should determine whether the handling of livestock is being done with a minimum of excitement and discomfort to the animals. Inspection program personnel will verify the moving of livestock, the availability of water and the handling of disabled livestock in the establishment. To do this, inspection program personnel need to seek answers to questions such as:

1. Are animals driven from the unloading ramps to the holding pens with a minimum of excitement and not at a running pace?

2. Are electric prods and other implements used as little as possible to move animals within the establishment?

3. Are animals driven by using an object that would not cause unnecessary pain (e.g., not using a sharp object or pipe)?
4. Are disabled animals separated from ambulatory animals and placed in a covered pen?
5. Do the animals have access to water?
6. Is there sufficient room in the holding pens for animals that are held over night?

The above questions are examples and are not an all-inclusive list.

NOTE: Verification of compliance with 9 CFR 313.2(d) that deals specifically with disabled livestock, is also addressed in FSIS Directive 6900.1, Humane Handling of Disabled Livestock.

C. What actions do inspection program personnel take if there is a noncompliance with 9 CFR 313.2?

If inspection program personnel observe a noncompliance with 9 CFR 313.2, they are to determine whether the situation does or will immediately lead to animal injury or inhumane treatment. If the noncompliance can be immediately remedied (e.g., providing water to penned animals), inspection program personnel are to take the action as set out in Part VI A 1 and 2. If an immediate remedy is not forthcoming (e.g., the establishment fails to provide water immediately after being notified that animals do not have water available), inspection program personnel are to take the action as set out in Part VI A 3. If the noncompliance is resulting in the injury or inhumane treatment of animals (e.g., the dragging of disabled animals), inspection program personnel are to take action as set out in Part VI B.

PART IV -- Stunning Methods

Appropriate stunning methods are required for an establishment to be in compliance with the HMSA. When stunning is done correctly, animals feel no pain, are rendered instantly unconscious, and remain unconscious until slaughtered. There are four methods of stunning approved for livestock. A summary of these approved stunning methods appear below (refer to 9 CFR sections 313.5, 313.15, 313.16 and 313.30).

A. What are the general regulatory requirements related to approved stunning methods?

Chemical; carbon dioxide

Regulatory requirements for the use of carbon dioxide as a humane method of slaughter are specified in section 313.5 and include, among other things, the following:

- 1) Carbon dioxide gas may be used to slaughter and handle sheep, calves and swine.

- 2) The carbon dioxide gas shall be administered in a chamber so as to produce surgical anesthesia (a state where an animal feels no painful sensation) before the animal is shackled, hoisted, thrown, cast, or cut. Animals shall be exposed to the carbon dioxide gas in a way that will accomplish the anesthesia quickly and calmly.
- 3) Gas concentrations and exposure times shall be graphically recorded throughout each day's operation.
- 4) It is necessary that the operator be skilled, attentive, and aware of his or her responsibility.

Mechanical; captive bolt

Regulatory requirements for the use of captive bolt stunners as a humane method of slaughter are specified in section 313.15 and include, among other things, the following:

- 1) Captive bolt stunners may be used to slaughter and handle sheep, swine, goats, calves, cattle, horses, mules, and other equines.
- 2) The captive bolt stunners shall be applied to livestock so as to produce immediate unconsciousness in the animals before they are shackled, hoisted, thrown, cast, or cut.
- 3) The stunning operation is an exacting procedure and requires a well-trained and experienced operator who must use the correct detonating charge with regard to kind, breed, size, age, and sex of the animal to produce the desired results.
- 4) Stunning instruments must be maintained in good repair.

Mechanical; gunshot

Regulatory requirements for the use of gunshot as a humane method of slaughter are specified in section 313.16 and include, among other things, the following:

- 1) Shooting by firearms may be used to slaughter and handle cattle, calves, sheep, swine, goats, horses, mules, and other equines.
- 2) A single shot delivery of a bullet or projectile into the animal is to produce immediate unconsciousness in the animal before it is shackled, hoisted, thrown, cast or cut.
- 3) Firearms must be maintained in good repair.
- 4) The shooting operation is an exacting procedure and requires a well-trained and experienced operator who must be able to accurately direct the projectile to produce immediate unconsciousness.
- 5) The operator must use the correct caliber firearm, powder charge and type of ammunition to produce instant unconsciousness in the animal.

Electrical; stunning or slaughtering with electric current

Regulatory requirements for the use of electric current as a humane method of slaughter are specified in section 313.30 and include, among other things, the following:

- 1) Electric current may be used to slaughter and handle swine, sheep, calves, cattle, and goats.

- 2) The animal shall be exposed to the electric current in a way that will accomplish surgical anesthesia (a state where an animal feels no painful sensation) quickly and effectively before they are shackled, hoisted, thrown, cast, or cut.
- 3) It is necessary that the operator of electric current application equipment be skilled, attentive, and aware of his or her responsibility.
- 4) Suitable timing, voltage and current control devices shall be used to ensure that each animal receives the necessary electrical charge to produce immediate unconsciousness.

B. How do inspection program personnel verify compliance with these regulations?

When verifying compliance with 9 CFR 313.5, 313.15, 313.16, and 313.30, inspection program personnel should assess the stunning method used for its effectiveness in rendering animals immediately unconscious and verify that animals are being properly stunned at the knocking box before hoisting. To do this, inspection program personnel need to seek answers to questions such as:

1. During stunning operations, is the establishment consistently rendering animals unconscious with a single application of the stunning methodology?
2. Is stunning equipment in good repair?
3. Are carbon dioxide gas concentrations graphically recorded throughout each day's stunning operation so that the correct amount of gas is used to adequately anesthetize an animal?
4. Is the captive bolt stunner accurately placed so that after it is applied the animal is immediately unconscious?
5. Is the correct caliber firearm being used to produce quick and complete unconsciousness in an animal?
6. Is the proper voltage of electric current being used so that the animal is quickly rendered unconscious?

NOTE: The above questions are examples and are not an all-inclusive list.

C. What actions do inspection program personnel take if there is a noncompliance with 9 CFR 313.5, 313.15, 313.16, or 313.30?

If inspection program personnel observe a noncompliance with 9 CFR 313.5, 313.15, 313.16, or 313.30, they are to determine whether the situation does or will immediately lead to animal injury or inhumane treatment. If the noncompliance is such that animals will not be injured or treated inhumanely (e.g., the gas concentration was not graphically recorded, but the establishment showed that the proper concentration was administered), inspection program personnel are to take an action as set out in Part VI A. If the noncompliance is resulting in the injury or inhumane treatment of animals (e.g., an animal is not properly rendered unconscious) inspection program personnel are to take action as set out in Part VI B.

PART V -- Ritual Slaughter of Livestock

A. General Requirement

Section 1902 (b) of the Humane Methods of Slaughter Act of 1978 provides that “slaughtering in accordance with the ritual requirements of the Jewish faith or any other religious faith that prescribes a method of slaughter whereby the animal suffers loss of consciousness by anemia of the brain caused by the simultaneous and instantaneous severance of the carotid arteries with a sharp instrument and handling in connection with such slaughtering” is humane.

Therefore, an establishment may slaughter in accordance with the requirements of Kosher, Halal (Islamic), or any other religious faith’s requirements. Inspection program personnel should not interfere with any slaughter procedures that are performed in accordance with such requirements. To enable inspection program personnel to be informed about what is occurring, they are to request that the establishment provide a written statement from an official of the religion who has authority over the enforcement of religious dietary laws that describes the ritual slaughter method that the faith prescribes, if this description has not been attached by the establishment to FSIS Form 5200-2, Application for Federal Meat, Poultry, or Import Inspection.

Although an operation may be performing exempted ritual slaughter, it is not exempted from other humane handling regulations in 9 CFR 313.1 and 313.2(a)-(e). Consequently, inspection program personnel are to verify that establishments that conduct ritual slaughter comply with the applicable regulatory requirements for humane handling contained in 9 CFR 313.1 and 313.2(a)-(e).

B. How do inspection program personnel verify that an establishment performing ritual slaughter meets the statutory and regulatory requirements for humane handling of livestock?

When verifying whether an establishment that performs ritual slaughter meets the regulatory requirements for humane handling, inspection program personnel should assess humane handling activities in all areas of the establishment as described in Parts II and III (except those discussions concerning stunning).

C. Are there circumstances in which it is appropriate for inspection program personnel to act under the HMSA to interrupt ritual slaughter?

Inspection program personnel may act under section 1902 (b) of the HMSA if, after the animal’s throat is cut, it struggles or bellows for an extended period of time or otherwise exhibits consciousness, or if the act of slaughter includes throat sawing, hacking, or multiple slicing of the neck with a sharp instrument. Such incidents are examples of noncompliance because either the cut of the carotid arteries is not instantaneous and simultaneous, or the animals do not lose consciousness by anemia of the brain. If any of the above incidents are observed, inspection program personnel are to take steps to ensure that the animal is immediately and humanely rendered unconscious and slaughtered.

D. What actions do inspection program personnel take if there is a noncompliance during ritual slaughter?

If inspection program personnel observe a noncompliance regarding ritual slaughter, resulting in the injury or inhumane treatment of animals (e.g., consciousness after the ritual procedure), inspection program personnel are to take action as set out in Part VI B.

PART VI – Enforcement and Documentation

A. What do inspection program personnel do when they have determined that a noncompliance with the humane slaughter and handling requirements has occurred that is not immediately causing injury or inhumane treatment of animals?

1. Inspection program personnel are to document the noncompliance on an FSIS Form 5400-4, Noncompliance Record (NR), under the Inspection System Procedure (ISP) code 04C02 using the “Protocol” trend indicator. Inspection program personnel are to specify the regulation or statutory provision that pertains to the incident, provide a concise description of the noncompliance and provide any other evidence that supports the determination that a noncompliance has occurred.

2. Inspection program personnel are to verify that the establishment takes the necessary immediate and further preventive actions.

3. If an establishment fails to adequately respond to an NR or fails to take its immediate and further preventive actions, inspection program personnel are to take a control action (i.e., apply a U.S. Reject Tag) as set out in 9 CFR 500.2 (a)(4), *inhumane handling or slaughter of livestock*. The control action will remain in place until the establishment implements the appropriate immediate and further preventive actions that ensure compliance with the appropriate section of 9 CFR part 313.

B. What do inspection program personnel do when they have determined that a noncompliance with the humane slaughter and handling requirements has occurred and animals are being injured or treated inhumanely?

1. Inspection program personnel are to document the noncompliance on an NR, under the ISP code 04C02 using the “Protocol” trend indicator. Inspection program personnel are to specify the regulation or statutory provision that pertains to the incident, provide a concise description of the noncompliance and provide any other evidence that supports the determination that a noncompliance has occurred.

2. Inspection program personnel are to take a control action (i.e., apply a tag) as set out in 9 CFR 500.2 (a)(4), *inhumane handling or slaughter of livestock*. The control action will remain in place until the establishment implements the appropriate immediate and further preventive actions that ensure compliance with the appropriate section of 9 CFR part 313.

C. How do inspection program personnel determine whether there is a trend of a noncompliance with the humane slaughter and handling requirements?

To determine whether a noncompliance trend exists, inspection program personnel will need to decide whether they can link NRs. Inspection program personnel should only link NRs when the noncompliances are from the same cause.

To make a determination as to whether a trend exists, inspection program personnel are to seek answer to the following questions:

1. How much time has lapsed since the previous NR was written?
2. Was this noncompliance from the same cause as the previous NR?
3. Were the establishment's further planned actions implemented?
4. Were the establishment's further planned actions effective in reducing the frequency of these noncompliances?
5. Is the establishment implementing additional planned actions that reduce the possibility of recurrence?

Inspection program personnel should be discussing any linkages with plant management during the weekly meetings. Inspection program personnel should also include in Block 10 of the NR that these discussions were held. Inspection program personnel should also include a statement in Block 10 of the NR stating that continued failure to meet regulatory requirements can lead to the enforcement actions described in 9 CFR 500.3(b).

Inspection program personnel should continue to link NRs together that derive from the same or a related cause until he or she determines that an enforcement action is necessary to bring the establishment into compliance with the regulations.

When inspection program personnel determine that an enforcement action (i.e., suspension as described in 9 CFR 500.3(b)) is necessary, they should contact the District Office (DO) and provide support for this determination.

The DO will determine whether inspection should be suspended as set out in 9 CFR 500.3(b). As provided in 9 CFR 500.3(b), FSIS may impose a suspension without providing the establishment prior notification if the establishment is handling or slaughtering animals inhumanely.

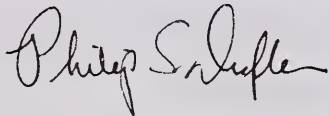
D. When may the Inspector-in-Charge (IIC) immediately suspend inspection because the establishment is handling or slaughtering animal inhumanely?

If there is an egregious situation of inhumane handling or slaughter, the IIC may immediately suspend inspection in accordance with 9 CFR 500.3(b) of the regulations. The IIC verbally notifies plant management of the suspension. In such situations, the IIC is to immediately notify the DO for prompt documentation of the suspension action.

PART VII - Information for the District Veterinary Medical Specialists (DVMS)

What do inspection program personnel provide to the DO to document noncompliance findings with the humane handling and slaughter requirements?

When noncompliances occur, inspection program personnel are to send copies of the NRs to the DVMS (or to the Deputy District Manager if there is no DVMS in a District). These NRs should be kept on file in the DO. When necessary, the DVMS or the Deputy District Managers will follow-up on issues of concern and will correlate resolutions.



Assistant Administrator
Office of Policy and Program Development

Attachment

Attachment 1**Humane Methods of Slaughter Act of 1978. (7 U.S.C. 1901 et seq.)****Sec. 1901. - Findings and declaration of policy**

The Congress finds that the use of humane methods in the slaughter of livestock prevents needless suffering; results in safer and better working conditions for persons engaged in the slaughtering industry; brings about improvement of products and economies in slaughtering operations; and produces other benefits for producers, processors, and consumers which tend to expedite an orderly flow of livestock and livestock products in interstate and foreign commerce. It is therefore declared to be the policy of the United States that the slaughtering of livestock and the handling of livestock in connection with slaughter shall be carried out only by humane methods.

Sec. 1902. - Humane methods

No method of slaughtering or handling in connection with slaughtering shall be deemed to comply with the public policy of the United States unless it is humane. Either of the following two methods of slaughtering and handling are hereby found to be humane:

(a) in the case of cattle, calves, horses, mules, sheep, swine, and other livestock, all animals are rendered insensible to pain by a single blow or gunshot or an electrical, chemical or other means that is rapid and effective, before being shackled, hoisted, thrown, cast, or cut; or

(b) by slaughtering in accordance with the ritual requirements of the Jewish faith or any other religious faith that prescribes a method of slaughter whereby the animal suffers loss of consciousness by anemia of the brain caused by the simultaneous and instantaneous severance of the carotid arteries with a sharp instrument and handling in connection with such slaughtering.

Section 1906 – Exemption of ritual slaughter

Nothing in this chapter (Humane Methods of Slaughter Act of 1978 – Title 7 of the U.S. Code, Chapter 48) shall be construed to prohibit, abridge, or in any way hinder the religious freedom of any person or group. Notwithstanding any other provision of this chapter, in order to protect freedom of religion, ritual slaughter and the handling or other preparation of livestock for ritual slaughter are exempted from the terms of this chapter. For the purposes of this section the term “ritual slaughter” means slaughter in accordance with section 1902(b) of this title.

**United States Department of Agriculture
Food Safety and Inspection Service
Printing Management Section, ASD
5601 Sunnyside Avenue, Mail Drop 5241
Beltsville, MD 20705-5241**

**OFFICIAL BUSINESS
Penalty for Private Use, \$300**

**FIRST-CLASS MAIL
POSTAGE & FEES PAID
USDA-FSIS
Permit No. G-42**

FSIS DIRECTIVE

200 FEB -9
DIR:17
7120.1

12/17/2002

SAFE AND SUITABLE INGREDIENTS USED IN THE PRODUCTION OF MEAT AND POULTRY PRODUCTS

I. PURPOSE

This directive provides inspection program personnel with an up-to-date list of approved substances for use in the production of meat and poultry products.

II. [RESERVED]

III. REFERENCES

9 CFR Chapter III

IV. RESERVED

V. BACKGROUND

A. On December 23, 1999, the Food Safety and Inspection Service (FSIS) published in the Federal Register a final rule on "Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products." The final rule streamlined the process for approving the use of food ingredients and sources of radiation in meat and poultry products to provide for the simultaneous review, by FSIS and the Food and Drug Administration (FDA), of petitions for new uses of food and color additives and notifications for new uses of generally recognized as safe (GRAS) substances that are submitted to FDA. Subsequent to the publication of the final rule in January, 2000, FDA and FSIS entered into a Memorandum of Understanding (MOU) that outlines the procedures that are followed by FDA and FSIS regarding the joint review of requests for the use of food ingredients and sources of radiation in meat and poultry products. Except in certain circumstances, FDA will now list in its regulations (21 CFR) food additives and sources of radiation that are safe and suitable for use in the production of meat or poultry products.

B. FDA regulations permit ingredient and food manufacturers to make their own determination that a particular use of a substance in food is GRAS by qualified experts. The substances that are determined to be GRAS through self-determinations are not listed in the FDA regulations in Title 21 of the CFR. However, on April 17, 1997, FDA published in the Federal Register a Proposed Rule that would establish a notification

DISTRIBUTION: Inspection Offices; T/A Inspectors;
Plant Mgt; T/A Plant Mgt; TRA; ABB; TSC, Import Offices

OPI: OPPD

procedure whereby any person may notify FDA of a determination that a particular use of a substance is GRAS. Although this proposed notification procedure is not yet final, FDA is operating in accordance with the proposal. FDA has received many GRAS notifications pertaining to meat and poultry products that are included in an Inventory of GRAS Notices that FDA has established on its Website. When a GRAS notification involves a use in a meat or poultry product, FDA's response to the notifier will include any restrictions or conditions of use of the substance in the production of meat or poultry products that FSIS recommends, provided such restrictions or conditions of use are consistent with Sections 201 and 409(s) of the Federal Food, Drug, and Cosmetic Act (FFDCA). The Inventory of GRAS Notices, and FDA's responses, may be accessed on the Internet World-Wide Web at: <http://vm.cfsan.fda.gov/~rdb/opa-gras.html>.

C. FDA also maintains an inventory of premarket notifications for food contact substances. However, unlike the GRAS notices, a premarket notification only applies to the manufacturer or supplier identified in the notification. In the process of reviewing notifications, FDA will consult with FSIS if the intended use involves meat or poultry, per the MOU. The FDA inventory of premarket notifications may be accessed on the Internet World-Wide Web at: <http://www.cfsan.fda.gov/~dms/opa-fcn.html>.

D. Substances listed approved in FDA regulations for use in food generally (21 CFR, Parts 172-180) or listed as GRAS for use in food (21 CFR, Parts 182 and 184) are not automatically acceptable as safe and suitable for use in meat and poultry products. Unless the approval or listing specifically mentions meat and poultry products, FSIS' Labeling and Consumer Protection Staff would need from FDA an affirmative written statement that FDA's safety determination did, in fact, consider use in meat or poultry, or that FDA does not have any objections with regard to the safety of the use in meat or poultry products. FSIS would still need to determine the suitability of the use of the substance, and whether rulemaking is required to permit such use. Provided FDA confirms the safety of the new use of a substance, or when FDA regulations already state that the substance is safe for use in food generally, FDA will not amend its regulations to list the specific use in meat and poultry products. However, rulemaking by FSIS may be necessary where a standard of identity prohibits or limits the use of an ingredient, or the ingredient is not expected in the product, e.g., adding milk to hamburger. If FSIS determines that rulemaking is necessary, the appropriate labeling or standards of identity regulation in Title 9 of the CFR will be amended to include the substance. In the event that rulemaking is not required, FSIS would notify the requestor, in writing, concerning the acceptable use in meat and poultry products (referred to as an "acceptability determination," as described in the MOU).

E. In the December 23, 1999, final rule, FSIS acknowledged the need to provide direction to its inspection program personnel concerning the use of food ingredients and sources of radiation that have been accepted by the Agency for use in meat and poultry products, but not listed in Titles 9 or 21 of the CFR. Consequently, FSIS proposed to maintain in its directive system, a comprehensive listing of the substances that have been reviewed according to the MOU and that have been accepted as safe and suitable by FSIS.

FSIS Directive 7120.1

F. The attachment below identifies the substances that have been accepted since January 2000 by FSIS as safe and suitable for use in the production of meat and poultry products that are not listed in 9 CFR 424.21(c). In order to be comprehensive, substances that have been approved in 21 CFR for use in meat and poultry as food additives; in GRAS notices and pre-market notifications, as well as in letters conveying acceptability determinations, have been included. This table is current as of November 25, 2002. The information is also available on the United States Department of Agriculture (USDA) website at www.fsis.usda.gov/OPPDE/larc/index.htm. For further policy information regarding any of the substances listed below please contact the Labeling and Consumer Protection Staff by telephone at Area Code (202) 205-0279 or by electronic mail at: FSIS.Labeling@fsis.usda.gov. FSIS issues quarterly updates to the list, as needed.



Deputy Administrator
Office of Policy and Program
Development

SUBSTANCE	PURPOSE/PRODUCT	AMOUNT	REFERENCE
<i>Anticoagulants</i>			
Sodium Tripolyphosphate	Sequestrant/anti-coagulant for use in recovered livestock blood which is subsequently used in food products	Not to exceed 0.5 percent of recovered blood	Acceptability determination
<i>Antimicrobials</i>			
A mixture of hops beta acids, egg white lysozyme, and cultured skim milk	In a salad dressing used in refrigerated meat and poultry deli salads	Not to exceed 1.5 percent of the salad dressing	Acceptability determination
Acidified sodium chlorite	Poultry carcasses and parts; meat carcasses, parts, and organs; processed, comminuted, or formed meat food products	500 to 1200 ppm in combination with any GRAS acid at a level sufficient to achieve a pH of 2.3 to 2.9 in accordance with 21 CFR 173.325 (<i>Note: The pH depends on the type of meat or poultry product.</i>)	21 CFR 173.325
Anhydrous ammonia	Lean finely textured beef which is subsequently quick chilled to 28 degrees Fahrenheit and mechanically "stressed"	In accordance with current industry standards of good manufacturing practice	Acceptability determination
Lactoferrin	Beef carcasses and parts	At up to 2 percent of a water-based antimicrobial spray	GRAS Notice 000067
Nisin Preparation	Components of sauces prepared under FDA jurisdiction and used with fully cooked meat or poultry	In sauces prepared under FDA jurisdiction that contain no more than 600 ppm nisin preparation may be used where the meat or poultry does not exceed 50 percent of the product formulation	Acceptability determination
Nisin Preparation	Meat and poultry soups	Not to exceed 5 ppm of the product formulation	Acceptability determination
Ozone	All meat and poultry products	In accordance with current industry standards of good manufacturing practice	21 CFR 173.368
Peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP)	Meat and poultry carcasses, parts, trim and organs	Maximum concentrations: Peroxyacetic acids 220 ppm, hydrogen peroxide 100 ppm	21 CFR 173.370
Potassium diacetate	Various meat and poultry products	Not to exceed 0.25 of the product formulation	Acceptability determination
Sodium citrate buffered with citric acid to a pH of 5.6	Non-standardized comminuted meat and poultry products	Not to exceed 1.3 percent of the product formulation in accordance with 21 CFR 184.1751	Acceptability determination

Trisodium Phosphate	Raw, unchilled poultry carcasses and giblets	8-12 percent solution applied by spraying or dipping giblets for up to 30 seconds. 8-12 percent solution within a temperature range of 65° F to 85 ° F applied by spraying or dipping carcasses for up to 15 seconds	Acceptability determination (per 21 CFR 182.1778)
<i>Antioxidants</i>			
BHA (butylated hydroxyanisole)	“Brown N Serve” sausages	0.02 percent in combination with other antioxidants for use in meat, based on fat content	Acceptability determination
BHT (butylated hydroxytoluene)	“Brown N Serve” sausages	0.02 percent in combination with other antioxidants for use in meat, based on fat content	Acceptability determination
<i>Binders</i>			
Binders listed in 9 CFR 424.21(c) for use in cured pork products and poultry products	Turkey ham and water products	In accordance with 9 CFR 319.104(d) and 424.21(c)	Acceptability determination
α-Cellulose from bamboo	Various non-standardized comminuted poultry products	Not to exceed 3.5 percent of the product formulation	Acceptability determination
Hydroxypropyl methylcellulose	Seasoning mixtures added to sauces and gravies produced under FDA jurisdiction that will be used in meat and poultry products	Sufficient for purpose	Acceptability determination
Hydroxypropyl methylcellulose	Thickener in meat and poultry pot pie fillings, sauces, soups, and gravies	Not to exceed 1 percent of the product formulation	Acceptability determination
Inulin	Various non-standardized meat and poultry products	2 to 5 percent of the product formulation	Acceptability determination
Konjac flour	Meat and poultry products in which starchy vegetable flours are permitted	No to exceed 3.5 percent of the product formulation individually or collectively with other binders	Acceptability determination
Methylcellulose	Various non-standardized comminuted meat and poultry products	Not to exceed 3.5 percent of the product formulation	Acceptability determination
Methylcellulose	Thickener in meat and poultry pot pie fillings, sauces, soups, and gravies; a binder in poultry patties, loaves, and nuggets; a binder in meat patties, loaves, and nuggets; texturizer in Policy Memo	Not to exceed 1 percent of the product formulation as a thickener in meat and poultry pot pie fillings, sauces, soups, and gravies; 1.6 percent as a binder in poultry patties, loaves, and nuggets; 0.25 percent as a binder in	Acceptability determination

	121B and 123 products	meat patties, loaves, and nuggets; 0.6 percent as a texturizer in Policy Memo 121B and 123 products	
Partially hydrolyzed proteins	Non-standardized meat and poultry products where binders are permitted. Standardized meat and poultry products with standards of identity that allow such use.	Not to exceed 3.5 percent of the product formulation	Acceptability determination
Pectin	Non-standardized meat and poultry products	Not to exceed 3 percent of the product formulation	Acceptability determination
Pork collagen	Non-standardized meat food products where binders are permitted and modified meat and poultry products addressed in Policy Memos 121B and 123	Not to exceed 3.5 percent of the product formulation	Acceptability determination
Sodium alginate	Various non-standardized meat products	Not to exceed 1 percent of the product formulation	Acceptability determination
Sodium alginate	Various non-standardized poultry products	Not to exceed 0.8 percent of the product formulation	Acceptability determination
Transglutaminase enzyme	Texturizing agent in non-standardized meat and poultry food products where texturizing agents and binders are permitted	Not to exceed 65 ppm of the product formulation	Acceptability determination
Transglutaminase enzyme	Cross-linking agent in modified meat and poultry products addressed in Policy Memos 121B and 123	Not to exceed 65 ppm of the product formulation	Acceptability determination
Coloring agent			
Carmine (cochineal)	To color textured soy protein isolate for use in dry cured acidified sausages	0.2 to 0.4 percent of the hydrated protein gel. The protein gel must not exceed 30 percent of the meat food product formulation	Acceptability determination
Curing Accelerators (must be used only in combination with curing agents)			
Potassium erythorbate	Cured pork and beef cuts; cured meat food products; cured comminuted poultry or poultry products	87.5 oz. to 100 gallons of pickle at 10 percent pump; 7/8 oz. to 100 lbs. Of meat, meat byproduct or poultry product; 10 percent to surfaces of cured meat cuts or poultry products prior to packaging (the use of such a solution shall not add a significant amount of moisture to the product)	Acceptability determination

<i>Film Forming Agents</i>			
A mixture of water, glycerin, carageenan, and cornstarch	Used to aid in the release of elastic netting on cooked meat products that are cooked in elastic netting	Sufficient for purpose	Acceptability determination
A mixture of water, glycerin, carageenan, cornstarch, and caramel	Used to aid in the release of elastic netting on cooked meat products that are cooked in elastic netting	Sufficient for purpose	Acceptability determination
A mixture of water, glycerin, carageenan, cornstarch, and smoke flavoring	Used to aid in the release of elastic netting on cooked meat products that are cooked in elastic netting	Sufficient for purpose	Acceptability determination
Gelatin spice sheets	To ensure even distribution of seasonings on cooked pork products	Sufficient for purpose	Acceptability determination
Hydroxypropyl methylcellulose	Film-forming agent in glazes for meat and poultry products	Not to exceed 4 percent of the product formulation	Acceptability determination
Methylcellulose	Film-forming agent in glazes for meat and poultry products	Not to exceed 3 percent of the product formulation for poultry products, 3.5 percent of the product formulation for meat products	Acceptability determination
<i>Flavoring Agents</i>			
Potassium acetate	Various meat and poultry products	No to exceed 1.2 percent of the product formulation	Acceptability determination
Sucralose	Non-nutritive sweetener in various non-standardized meat and poultry products	Not to exceed 500 ppm in the product formulation	Acceptability determination
<i>Miscellaneous</i>			
Cellulose (powdered)	To facilitate grinding and shredding in cheese	No to exceed 2 percent of the cheese	Acceptability determination
Erythorbic Acid	To delay discoloration in ground beef and ground beef patties	Not to exceed 0.04 percent of the product formulation (Must be descriptively labeled to distinguish from traditional standardized products)	Acceptability determination
Hydrogen peroxide	To minimize biofilm buildup on reverse osmosis and ultrafiltration membranes for processing beef plasma	No to exceed 100 ppm added just prior to plasma entering membranes	Acceptability determination
Small planktivorous pelagic fish oil	For use as an alternative edible oil in the production of various meat, poultry, and egg products	Not to exceed 6.7 percent of the product formulation	GRAS Notice 000102
Sodium bicarbonate	Neutralize excess acidity (maintain pH) in fresh pork and beef cuts	In an injected solution, not to exceed 0.5 percent of the product formulation	Acceptability determination

Sodium bicarbonate	Maintain pH and reduce purge in fresh turkey products	In an injected solution, not to exceed 0.5 percent of the product formulation	Acceptability determination
Sodium bicarbonate	To soak natural casings to ease stuffing	1.06 percent of an aqueous solution. Casings must be rinsed with potable water prior to stuffing	Acceptability determination
Xanthan gum	Suspending agent for carrageenan in a brine tank	Not to exceed 2 percent of the amount of carrageenan	Acceptability determination
Packaging Systems			
Carbon monoxide gas as part of the Pactiv modified atmosphere packaging system (ActiveTech 2001)	Packaging fresh cuts of case ready muscle meat and case ready ground meat to maintain wholesomeness, provide flexibility in distribution, and reduce shrinkage of the meat.	The use of carbon monoxide (0.4 percent), carbon dioxide (30 percent) and nitrogen (69.6) as part of the Pactiv modified atmosphere packaging system (ActiveTech 2001)	GRAS Notice 000083
Tenderizing Agents			
Calcium gluconate	Raw meat products	Solutions applied or injected into raw meat shall not result in a gain of 3 percent above green weight	Acceptability determination
Protease preparation derived from <i>Bacillus subtilis</i>	Raw meat products	Solutions applied or injected into raw meat shall not result in a gain of 3 percent above green weight	Acceptability determination
Protease produced from <i>Bacillus subtilis</i> var. <i>amyloliquefaciens</i>	Raw meat products	Solutions applied or injected into raw meat shall not result in a gain of 3 percent above green weight	Acceptability determination

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

USDA
CHANGE TRANSMITTAL SHEET

☐ DIRECTIVE
☐ REVISION
☒ AMENDMENT
☐ OTHER

Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products	7120.1, Amend 1	11/3/03
---	-----------------	---------

I. PURPOSE

This transmittal issues changes to Attachment 1 and a new Attachment 2 for FSIS Directive 7120.1.

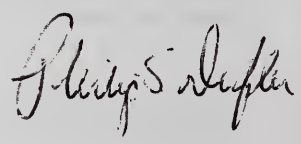
Attachment 1 identifies the substances that have been approved in 21 CFR for use in meat and poultry products as food additives, approved in GRAS notices and pre-market notifications, and approved in letters conveying acceptability determinations. Substances added since the 12/17/2002 issuance of the directive are in bold. This information is also available on the USDA website at: www.fsis.usda.gov/OPPDE/larc/index.htm. For further policy information regarding any of the substances listed below please contact the New Technology Staff by telephone at Area Code (202) 205-0675. FSIS will continue to issue updates to the list, as needed.

NOTE: Attachment 1 does not include the use of substances in on-line reprocessing operations that operate under an experimental exemption listed in 9 CFR 381.3(c). Establishments operating under this exemption should follow the conditions of use that are specific to their FSIS approved on-line reprocessing protocol.

This change transmittal also issues an Attachment 2 that presents questions and answers that relate to the use of antimicrobial agents on raw and processed meat and poultry products.

II. CANCELLATION

This transmittal is cancelled when contents have been incorporated into FSIS Directive 7120.1.



Assistant Administrator
Office of Policy and Program Development

FILING INSTRUCTION

<u>Remove Old Pages</u>	<u>Insert New Pages</u>
4-8	4-18

DISTRIBUTION: Inspection Offices, T/A Inspectors,
Plant Mgt., T/A Plant Mgt., TRA, ABB, TSC, Import
Offices

OPI: OPPD

Table of Safe and Suitable Ingredients

SUBSTANCE	PRODUCT	AMOUNT	REFERENCE	LABELING REQUIREMENTS
Anticoagulants				
Sodium tripolyphosphate	Sequestrant/anti-coagulant for use in recovered livestock blood which is subsequently used in food products	Not to exceed 0.5 percent of recovered blood	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Antimicrobials				
A mixture of hops beta acids, egg white lysozyme, and cultured skim milk	In a salad dressing used in refrigerated meat and poultry deli salads	Not to exceed 1.5 percent of the finished salad	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Acidified sodium chlorite	Poultry carcasses and parts; meat carcasses, parts, and organs; processed, comminuted, or formed meat food products	500 to 1200 ppm in combination with any GRAS acid at a level sufficient to achieve a pH of 2.3 to 2.9 in accordance with 21 CFR 173.325 (<i>Note: The pH depends on the type of meat or poultry product.</i>)	21 CFR 173.325	None under the accepted conditions of use (3)
Acidified sodium chlorite	Processed, comminuted or formed poultry products	500 to 1200 ppm in combination with any GRAS acid at a level sufficient to achieve a pH of 2.3 to 2.9 in accordance with 21 CFR 173.325 (<i>Note: The pH depends on the type of meat or poultry product.</i>)	Acceptability determination	None under the accepted conditions of use (3)
Anhydrous ammonia	Lean finely textured beef which is subsequently quick chilled to 28 degrees Fahrenheit and mechanically "stressed"	In accordance with current industry standards of good manufacturing practice	Acceptability determination	None under the accepted conditions of use (1)
DBDMH (1,3dibromo-5,5-dimethylhydantoin)	For use in poultry chiller water	At a level not to exceed 100 ppm active bromine	Food Contact Substance Notification No. FCN 334	None under the accepted conditions of use (6)
Egg white lysozyme	In casings and on cooked (RTE) meat and poultry products	2.5 mg per pound in the finished product when used in casings; 2.0 mg per pound on cooked meat and poultry products	GRAS Notice No. 000064	Listed by common or usual name in the ingredients statement (2)

A blend of citric acid (1.87%), phosphoric acid (1.72%), and hydrochloric acid (0.8%)	Poultry carcasses	Dipped in solution, allowed to drip for 30 seconds, and rinsed with a spray application of water for 1-2 seconds	Acceptability determination	None under the accepted conditions of use (1)
A blend of citric acid, hydrochloric acid, and phosphoric acid	To adjust the acidity in various meat and poultry products	Sufficient for purpose	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Hops beta acids	In casings and on cooked (RTE) meat and poultry products	2.5 mg per pound in the finished product when used in casings; 2.0 mg per pound on cooked meat and poultry products	GRAS Notice No. 000063	Listed by common or usual name in the ingredients statement (2)
Lactic Acid	Beef carcasses prior to fabrication (i.e., pre- and post-chill)	Hot (≈55° C) 5 percent lactic acid solution	Acceptability determination	None under the accepted conditions of use (1)
Lactoferrin	Beef carcasses and parts	At up to 2 percent of a water-based antimicrobial spray	GRAS Notice No. 000067	Listed by common or usual name in ingredients statement (2)
Lactoferrin	Beef carcasses	As part of an antimicrobial spray that would deliver 1 gram of lactoferrin per dressed beef carcass, followed by a wash with tempered water and rinse with lactic acid	GRAS Notice No. 000130	None under the accepted conditions of use (1)
Nisin preparation	Components of sauces prepared under FDA jurisdiction and used with fully cooked meat or poultry	In sauces prepared under FDA jurisdiction that contain no more than 600 ppm nisin preparation may be used where the meat or poultry does not exceed 50 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Nisin	Meat and poultry soups	Not to exceed 5 ppm of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Nisin	In casings and on cooked (RTE) meat and poultry products	3.15 mg per pound in the finished product when used in casings; 2.5 mg per pound on cooked meat and poultry products	GRAS Notice No. 000065	Listed by common or usual name in the ingredients statement (2)
Organic Acids (i.e., lactic, acetic, and citric acid)	As part of carcass wash applied pre-chill	At up to 2.5 percent of a solution	FSIS Notice 49-94	None under the accepted conditions of use (1)

Ozone	All meat and poultry products	In accordance with current industry standards of good manufacturing practice	21 CFR 173.368	None under the accepted conditions of use (3)
Peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP)	Meat and poultry carcasses, parts, trim and organs	Maximum concentrations for meat carcasses, parts, and organs: Peroxyacetic acids 220 ppm, hydrogen peroxide 75 ppm; Maximum concentrations for poultry carcasses, parts, and organs: Peroxyacetic acids 220 ppm, hydrogen peroxide 110 ppm, HEDP 13 ppm	21 CFR 173.370	None under the accepted conditions of use (3)
A mixture of Peroxyacetic acid, hydrogen peroxide, acetic acid, and 1-hydroxyethylidene-1, 1-diphosphonic acid (HEDP)	Process water for washing, rinsing, cooling, or otherwise for processing meat carcasses, parts, trim, and organs; and (2) process water applied to poultry carcasses as a spray, wash, rinse, dip, chiller water, or scald water	In either application, the level of Peroxyacetic acid will not exceed 230 ppm, hydrogen peroxide will not exceed 165 ppm, and HEDP will not exceed 14.0 ppm	Food Contact Substance Notification No. FCN 000323	None under the accepted conditions of use (6)
Potassium diacetate	Various meat and poultry products which permit the addition of antimicrobial agents, e.g., hot dogs	Not to exceed 0.25 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
A solution of water, lactic acid, propionic acid, and acidic calcium sulfate (solution with a pH range of 1.0-2.0)*	RTE meat products which permit the addition of antimicrobial agents, e.g., hot dogs	Applied as a spray for 20-30 seconds of continual application just prior to packaging <i>*Propionic acid may be removed from the solution; sodium phosphate may be added to the solution as a buffering agent (the amount of sodium phosphate on the finished product must not exceed 5000ppm)</i>	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Sodium citrate buffered with citric acid to a pH of 5.6	Non-standardized and standardized comminuted meat and poultry products which permit ingredients of this type	Not to exceed 1.3 percent of the product formulation in accordance with 21 CFR 184.1751	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Sodium metasilicate	Raw beef carcasses, subprimals, and trimmings	For use at up to 4 percent (plus or minus 2 percent) of a solution	Acceptability determination	None under the accepted conditions of use (1)

Trisodium phosphate	Raw unchilled poultry carcasses and giblets	8-12 percent solution applied by spraying or dipping giblets for up to 30 seconds. 8-12 percent solution within a temperature range of 65° F to 85 ° F applied by spraying or dipping carcasses for up to 15 seconds	Acceptability determination (per 21 CFR 182.1778)	None under the accepted conditions of use (1)
Antioxidants				
BHA (butylated hydroxyanisole)	“Brown N Serve” sausages	0.02 percent in combination with other antioxidants for use in meat, based on fat content	Acceptability determination	Listed by common or usual name in the ingredients statement (4)
BHT (butylated hydroxytoluene)	“Brown N Serve” sausages	0.02 percent in combination with other antioxidants for use in meat, based on fat content	Acceptability determination	Listed by common or usual name in the ingredients statement (4)
Binders				
Binders listed in 9 CFR 424.21(c) for use in cured pork products and poultry products	“Turkey ham and water products”	In accordance with 9 CFR 319.104(d) and 424.21(c)	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
α-Cellulose from bamboo	Various comminuted poultry products where binders are permitted	Not to exceed 3.5 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Carrot Fiber	Various comminuted meat and poultry products where binders are permitted	Not to exceed 3.5 percent of the product formulation	GRAS Notice No. 000116	List as “isolated carrot product” (2)
Hydroxypropyl methylcellulose	Seasoning mixtures added to sauces and gravies produced under FDA jurisdiction that will be used in meat and poultry products	Sufficient for purpose	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Hydroxypropyl methylcellulose	Thickener in meat and poultry pot pie fillings, sauces, soups, and gravies	Not to exceed 1 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Inulin	Various meat and poultry products (e.g., frankfurters, sausage, patties, loaves, pates) where binders are permitted	2 to 5 percent of the product formulation	Acceptability determination and GRAS Notice No. 000118	Listed by common or usual name in the ingredients statement (2)
Konjac flour	Meat and poultry products in which starchy vegetable flours are permitted	No to exceed 3.5 percent of the product formulation individually or collectively with other binders	Acceptability determination	Listed by common or usual name in the ingredients statement (2)

FSIS Directive 7120.1, Amendment 1
Attachment 1

Methylcellulose	Various comminuted meat and poultry products where binders are permitted	Not to exceed 3.5 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Methylcellulose	Thickener in meat and poultry pot pie fillings, sauces, soups, and gravies; a binder in poultry patties, loaves, and nuggets; a binder in meat patties, loaves, and nuggets; texturizer in Policy Memo 121B and 123 products	Not to exceed 1 percent of the product formulation as a thickener in meat and poultry pot pie fillings, sauces, soups, and gravies; 1.6 percent as a binder in poultry patties, loaves, and nuggets; 0.25 percent as a binder in meat patties, loaves, and nuggets; 0.6 percent as a texturizer in Policy Memo 121B and 123 products	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Partially hydrolyzed proteins	Various meat and poultry products where binders are permitted.	Not to exceed 3.5 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Pectin	Various meat and poultry products where binders are permitted	Not to exceed 3 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Pork collagen	Various meat and poultry food products where binders are permitted	Not to exceed 3.5 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Sodium alginate	Various meat products where binders are permitted	Not to exceed 1 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Sodium alginate	Various poultry products where binders are permitted	Not to exceed 0.8 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Transglutaminase enzyme	Texturizing agent in meat and poultry food products where texturizing agents and binders are permitted	Not to exceed 65 ppm of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Transglutaminase enzyme	Cross-linking agent in modified meat and poultry products addressed in Policy Memos 121B and 123	Not to exceed 65 ppm of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Trehalose	Binding and purge control agent in various meat and poultry products where binders are permitted	Not to exceed 2 percent of the product formulation	GRAS Notice No. 000045	Listed by common or usual name in the ingredients statement (2)

Xanthan gum (purified by recovery with ethyl alcohol)	Various meat and poultry products where binders are permitted	Non-standardized meat and poultry products and products with a standard of identity which currently permit the use of xanthan gum listed in 9 CFR 424.21(c)	GRAS Notice No. 000121	Listed by common or usual name in the ingredients statement (4)
Coloring Agents				
Carmine (cochineal)	To color textured soy protein isolate for use in dry cured acidified sausages	0.2 to 0.4 percent of the hydrated protein gel. The protein gel must not exceed 30 percent of the meat food product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (5)
Curing Accelerators (must be used only in combination with curing agents)				
Potassium erythorbate	Cured pork and beef cuts; cured meat food products; cured comminuted poultry or poultry products	87.5 oz. to 100 gallons of pickle at 10 percent pump; 7/8 oz. to 100 lbs. Of meat, meat byproduct or poultry product; 10 percent to surfaces of cured meat cuts or poultry products prior to <i>packaging</i>	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Film Forming Agents				
A mixture of water, glycerin, carrageenan, and cornstarch	Used to aid in the release of elastic netting on cooked meat products that are cooked in elastic netting	Sufficient for purpose	Acceptability determination	None under the accepted conditions of use (1)
A mixture of water, glycerin, carageenan, cornstarch, and caramel	Used to aid in the release of elastic netting on cooked meat products that are cooked in elastic netting	Sufficient for purpose	Acceptability determination	"Caramel Color" listed as an ingredient and as a product name qualifier (2)
A mixture of water, glycerin, carageenan, cornstarch, and smoke flavoring	Used to aid in the release of elastic netting on cooked meat products that are cooked in elastic netting	Sufficient for purpose	Acceptability determination	"Smoke Flavor" listed as an ingredient and as a product name qualifier (2)
Gelatin spice sheets	To ensure even distribution of seasonings on cooked pork products	Sufficient for purpose	Acceptability determination	None under the accepted conditions of use (1)

FSIS Directive 7120.1, Amendment 1
Attachment 1

Hydroxypropyl methylcellulose	Film-forming agent in glazes for meat and poultry products	Not to exceed 4 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Methylcellulose	Film-forming agent in glazes for meat and poultry products	Not to exceed 3 percent of the product formulation for poultry products, 3.5 percent of the product formulation for meat products	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Flavoring Agents				
Laminaria japonica	As a flavor enhancer or flavoring agent in marinades for meat and poultry, meat and poultry soups, gravies, and seasonings	Not to exceed 0.08 percent of the product formulation	GRAS Notice No. 000123	Listed by common or usual name in the ingredients statement (2)
Potassium acetate	Various meat and poultry products	No to exceed 1.2 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (4)
Sucralose	Non-nutritive sweetener in various non-standardized meat and poultry products	Not to exceed 500 ppm in the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Miscellaneous				
Cellulose (powdered)	To facilitate grinding and shredding in cheese	No to exceed 2 percent of the cheese	Acceptability determination	None under the accepted conditions of use (1)
Diacylglycerol oil	For use as an alternative edible oil in the production of various meat and poultry products	Not to exceed 11 percent of the meat or poultry product formula	GRAS Notice No. 000115	Listed by common or usual name in the ingredients statement (2)
Erythorbic Acid	To delay discoloration in ground beef and ground beef patties	Not to exceed 0.04 percent of the product formulation	Acceptability determination	Product must be descriptively labeled (2)
Fish oil concentrate	For use as an alternative edible oil in the production of various meat products	Not to exceed 5.7 percent of the product formulation	GRAS Notice No. 000105	Listed by common or usual name in the ingredients statement (2)
Hydrogen peroxide	To minimize biofilm buildup on reverse osmosis and ultrafiltration membranes for processing beef plasma	No to exceed 100 ppm added just prior to plasma entering membranes	Acceptability determination	None under the accepted conditions of use (1)
Small planktivorous pelagic fish oil	For use as an alternative edible oil in the production of various meat products	Not to exceed 6.7 percent of the product formulation	GRAS Notice No. 000102	Listed by common or usual name in the ingredients statement (2)
Sodium bicarbonate	Neutralize excess acidity (maintain pH) in fresh pork and beef cuts	In an injected solution, not to exceed 0.5 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)

Sodium bicarbonate	Maintain pH and reduce purge in fresh turkey products	In an injected solution, not to exceed 0.5 percent of the product formulation	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Sodium bicarbonate	To soak natural casings to ease stuffing	1.06 percent of an aqueous solution. Casings must be rinsed with potable water prior to stuffing	Acceptability determination	None under the accepted conditions of use (1)
Sodium hydroxide and hydrochloric acid	To adjust the pH of (species) plasma during processing (in which it is exposed to heat) to prevent gelling	Sufficient for purpose to adjust pH	Acceptability determination	None under the accepted conditions of use (1)
Tuna oil	For use as an alternative edible oil in the production of various meat products	Not to exceed 6.2 percent of the product formulation	GRAS Notice No. 000109	Listed by common or usual name in the ingredients statement (2)
Xanthan gum	Suspending agent for carrageenan in a brine tank	Not to exceed 2 percent of the amount of carrageenan	Acceptability determination	None under the accepted conditions of use (1)
Packaging Systems				
Carbon monoxide gas as part of Cryovac's modified atmosphere packaging system (for use with 550P Tray/Lid)	Packaging fresh cuts of case ready muscle meat and case ready ground meat to maintain wholesomeness, provide flexibility in distribution, and reduce shrinkage of the meat	The use of carbon monoxide (0.4 %), carbon dioxide (30 %) and nitrogen (69.6 %) as part of the Cryovac low oxygen modified atmosphere packaging system used with 550P Tray /Lid	Acceptability Determination	None under the accepted conditions of use (2)
Carbon monoxide gas as part of the Pactiv modified atmosphere packaging system (ActiveTech 2001)	Packaging fresh cuts of case ready muscle meat and case ready ground meat to maintain wholesomeness	The use of carbon monoxide (0.4 %), carbon dioxide (30 %) and nitrogen (69.6 %) as part of the Pactiv modified atmosphere packaging system	GRAS Notice No. 000083	None under the accepted conditions of use (2)
Tenderizing Agents				
Calcium gluconate	Raw meat products	Solutions applied or injected into raw meat shall not result in a gain of 3 percent above green weight	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Protease preparation derived from <i>Bacillus subtilis</i>	Raw meat products	Solutions applied or injected into raw meat shall not result in a gain of 3 percent above green weight	Acceptability determination	Listed by common or usual name in the ingredients statement (2)
Protease produced from <i>Bacillus subtilis</i> var. <i>amyloliquefaciens</i>	Raw meat products	Solutions applied or injected into raw meat shall not result in a gain of 3 percent above green weight	Acceptability determination	Listed by common or usual name in the ingredients statement (2)

- 1) The use of the substance(s) is consistent with FDA's labeling definition of a processing aid.
 - 2) Generally Recognized as Safe (GRAS)
 - 3) Secondary Direct Food Additive
 - 4) Direct Food Additive
 - 5) Color Additive
 - 6) Food Contact Substance
- * Substances identified in bold print in the table are substances that have been added to the directive since it was last issued on December 17, 2002.

Questions and Answers on the Use of Antimicrobial Agents in the Production of Meat and Poultry Products

The following set of questions and answers provide information regarding the requirements for the use of antimicrobial agents in meat and poultry production.

References

- Final Rule, "Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products" (December 1999).
- MOU between FDA and FSIS for Ingredient Approval (January, 2000).
- FSIS Directive 7120.1, "Safe and Suitable Ingredients Used in the Production of Meat and Poultry Products."
- Guidance document on "Ingredients and Sources of Radiation Used to Reduce Microorganisms on Carcass, Ground Beef and Beef Trimmings."
- Federal Register* Notice, "FSIS Procedures for Notification of New Technology" (68 FR 6873) (February, 2003)
- 9 CFR 416.4
- FSIS Directive 6355.1, "Use of Chlorine Dioxide in Poultry Chill Water."
- 9 CFR 424.21(c)
- FSIS Directive 6700.1, "Retained Water in Raw Meat and Poultry Products."
- 21 CFR Part 172, 173, 182, 184
- 21 CFR 101.100(a)(3)(ii)

1. Question: What is the definition of a New Technology?

Answer: According to the FSIS *Federal Register* Notice (68 FR 6873) entitled, "FSIS Procedures for Notification of New Technology," FSIS defines a "new technology" as new, or new applications of, equipment, substances, methods, processes or procedures affecting the slaughter of livestock and poultry or processing of meat, poultry, or egg products which could affect product safety, inspection procedures, inspection program personnel safety, or require a waiver of a regulation.

2. Question: What is the definition of a processing aid?

Answer: According to the Food and Drug Administration's (FDA) regulations (21 CFR 101.100 (a) (3) (ii)), the definition of a processing aid is:

- a. Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.
- b. Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in food.
- c. Substances that are added to a food for their technical or functional effect in the processing but

are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

An example of a processing aid is the use of organic acid(s) (e.g., lactic, acetic, or citric acid) to treat livestock carcasses at up to 2.5% of a solution applied pre-chill.

3. Question: What are secondary direct food additives and direct food additives?

Answer: According to FDA's regulations (21 CFR Part 173), secondary direct food additives are substances whose functionality is required during the manufacture or processing of a food and are ordinarily removed from the final food. Although residuals might carry over to the final food, residuals must not exhibit any technical effects. Secondary direct food additives are consistent with FDA's definition of a processing aid so labeling is not required. Examples of secondary direct food additives are acidified sodium chlorite (21 CFR 173.325) and peroxyacids (21 CFR 173.370).

According to FDA's regulations (21 CFR Part 172), direct food additives are used to provide a technical effect in the final food. The antioxidants BHA and BHT are examples of substances that are approved as direct food additives.

4. Question: Do organic acid(s) (e.g., lactic, acetic, or citric acid) that are used as antimicrobial agents need to be declared on the label if they are applied to livestock carcasses after the chilling step?

Answer: Organic acid(s) are generally recognized as safe (GRAS) and are listed in FSIS regulations for use as an acidifier in various meat and poultry products at a level which is sufficient for purpose (9 CFR 424.21(c)). All ingredients, including organic acid(s), require labeling unless the use of a substance is consistent with FDA's definition of a processing aid or is a secondary direct food additive.

FSIS has recently stated no objection to the use of 5% hot lactic acid as an antimicrobial agent to treat beef carcasses prior to fabrication (i.e., pre and post-chill). Data was submitted to the Agency that demonstrated no lasting effect under the specified conditions of use. FSIS determined that the proposed use is consistent with the definition of a processing aid. Therefore, its use would not need to be reflected on the labeling for treated carcasses or products produced from treated carcasses. This new use is listed in the table of this directive.

If a company is interested in using one or more of these organic acid(s) as an antimicrobial agent on livestock carcasses or trim in a manner other than that which is currently approved, they must provide data to the Agency that show that the use complies with FDA's definition of a processing aid. The data must show that the organic acid has only a momentary technical effect, not a lasting effect, on the meat, e.g., fresh color is not preserved, normal spoilage indicators (e.g. discoloration) are not masked; and there is no extension of shelf life as compared to products made with untreated trimmings. The data must also show that the nutrient composition is not affected by the treatment

and the sensory characteristics of the product are not affected. (Note: the reference to “Guidance on Ingredients and Sources of Radiation used to Reduce Microorganisms on Carcasses, Ground Beef, and Beef Trim,” can be accessed at [http: www.fsis.usda.gov/oppde/larc](http://www.fsis.usda.gov/oppde/larc) at the “ingredients” link)

5. Question: What is the maximum amount of organic acid(s) permitted to be applied to livestock carcasses pre-chill without having to declare the organic acid(s) on the label?

Answer: Historically, the maximum amount of organic acid(s) that can be used to treat livestock carcasses without labeling is up to 2.5% of a solution applied pre-chill. Labeling is not required for this specific use of organic acid(s) (which the Agency has permitted for many years) because it is based on data that showed that this application is consistent with FDA’s definition of a processing aid.

Recently, FSIS stated no objection to the use of 5% hot lactic acid as an antimicrobial agent on beef carcasses prior to fabrication (see question number four). This use was determined to be consistent with the definition of a processing aid. Therefore, its use would not need to be reflected on the labeling for treated carcasses or products produced from treated carcasses.

6. Question: Do organic acid(s) (e.g., lactic, acetic, or citric acid) that are used as antimicrobial agents need to be declared on the label if they are applied to livestock carcasses at a concentration above 2.5%?

Answer: Unless the proposed use has been determined by FSIS to be consistent with the definition of a processing aid (e.g., the application of organic acids at 2.5% of a beef carcass wash solution applied pre-chill or the application of 5 percent hot lactic acid solution to pre or post chilled beef carcasses prior to fabrication), the organic acid(s) would require labeling.

7. Question: Is the maximum amount of organic acid(s) allowed, without labeling the product, based on the concentration of the organic acid(s) applied to the carcass or the concentration of the organic acid(s) draining from the carcass?

Answer: The amount of organic acid(s) is based on the percentage of organic acid(s) in the carcass wash (aqueous solution) prior to application. It is not based on the residual level of organic acid(s) draining from a treated carcass during application.

8. Question: Do organic acid(s) (e.g. lactic, acetic, or citric acid) have to be declared on the label if they are applied to cut-up and ground meat and poultry?

Answer: Yes, all ingredients, including organic acid(s), require labeling unless the use of a substance is consistent with FDA’s definition of a processing aid or is a secondary direct food additive. If an establishment is interested in using organic acid(s) to treat meat and poultry cuts and/or ground meat and poultry to momentarily reduce microorganisms, data must be submitted to FSIS to show that the proposed use of organic acid(s) is consistent with FDA’s definition of a processing aid.

9. Question: Do organic acid(s) (e.g. lactic, acetic, or citric acid) have to be declared on the label if they are applied to livestock or poultry byproducts and giblets (e.g. livers, hearts, and gizzards)?

Answer: No, labeling is not required when organic acid(s) are applied pre-chill at up to 2.5% of an aqueous solution to treat livestock and poultry byproducts and giblets.

10. Question: Are organic acid(s) used as antimicrobial agents permitted to be used on poultry carcasses?

Answer: Yes, organic acid(s) are GRAS and are listed in FSIS regulations for use as an acidifier (which may have an antimicrobial effect) in various meat and poultry products at a level which is sufficient for purpose (9 CFR 424.21(c)). Organic acid(s) are permitted to be applied to poultry carcasses pre-chill at a concentration of up to 2.5 percent of a solution without labeling.

11. Question: If organic acid(s) (e.g., lactic, acetic, or citric acid) are used on ready-to-eat products as a spray or dip, must the application be followed by a potable water rinse?

Answer: No, the use of organic acid(s) on ready-to-eat products are not required to be followed by a potable water rinse. However, the organic acid(s) will be considered ingredients that require labeling unless data can be submitted to FSIS that show that their use is consistent with FDA's definition of a processing aid.

12. Question: Are organic acid(s) (e.g., lactic, acetic or citric acid) permitted to be used on a continuous basis on conveyor belts? What are the conditions for their use? When do the organic acids need to be declared on a product label?

Answer: FSIS has no objection to the use of organic acids on conveyor belts on a continuous basis. However, the process should not result in the organic acid(s) having a lasting technical effect on meat or poultry which comes into contact with the conveyor belts. Labeling is required if the organic acid(s) exhibit a lasting technical effect on meat or poultry which comes into contact with the treated conveyor belts.

13. Question: Are antimicrobial agents other than organic acid(s) permitted to be used on a continuous basis on conveyor belts if they are approved as an antimicrobial agent in the production of meat and poultry products? What are the conditions for their use? When do the antimicrobial agents have to be included on a product label?

Answer: Yes, antimicrobial agents approved for use in the production of meat and poultry products may be used on conveyor belts provided they are followed by a potable water rinse. Substances listed in 21 CFR 178.1010 may be used in sanitizing solutions on food contact surfaces with only adequate draining (no water rinse) before contact with food.

14. Question: Is trisodium phosphate (TSP) permitted to be used as an antimicrobial agent on livestock carcasses, viscera, and parts?

Answer: TSP may only be used on livestock carcasses according to interim Agency policy.

15. Question: Where is TSP allowed to be used as an antimicrobial agent on poultry?

Answer: FSIS regulations (9 CFR 424.21 (c)) permit the use of TSP on raw post-chill poultry carcasses. In addition, FSIS has permitted the application of TSP to raw poultry carcasses pre-chill by spraying or dipping the carcasses with an 8-12% solution maintained within a temperature range of 65° F to 85° F for up to 15 seconds. FSIS has permitted the spraying or dipping of poultry giblets for up to 30 seconds with an 8-12% solution of TSP pre-chill.

TSP is also used in some on-line reprocessing operations. Establishments which use on-line reprocessing operate under an experimental exemption listed in 9 CFR 381.3(c). The conditions of use for TSP in on-line reprocessing are limited by the parameters listed in the FSIS approved on-line reprocessing protocol, not the conditions of use listed above.

16. Question: Is chlorine dioxide permitted to be used as an antimicrobial agent on livestock carcasses, viscera, and parts?

Answer: No.

17. Question: Is chlorine dioxide allowed to be used as an antimicrobial agent on poultry? What are the conditions for its use?

Answer: Chlorine dioxide may be used as an antimicrobial agent to treat water in poultry processing as prescribed in FDA's regulations (21 CFR 173.300). Residual chlorine dioxide must not exceed 3 ppm in the poultry processing water.

18. Question: Is hydrogen peroxide allowed to be used as an antimicrobial agent on meat and poultry products (e.g. carcasses, parts, processed products)?

Answer: No, hydrogen peroxide is listed as GRAS in FDA regulations (21 CFR 184.1366) for use as a bleaching agent to treat beef feet and in FSIS regulations (9 CFR 424.21 (c)) as a bleaching agent to treat tripe (followed by a water rinse). It is also a component of peroxyacids (21 CFR 173.370).

19. Question: Can any and all anti-microbial agents be used on poultry carcasses during on-line reprocessing?

Answer: No, on-line reprocessing operations function under an experimental exemption (9 CFR 381.3 (c)). The use of antimicrobial agents in on-line reprocessing are limited by the parameters of the FSIS approved on-line reprocessing protocol.

20. Question: Can antimicrobial agents be used (spray or dip) on the same carcasses or parts more than once, without labeling?

Answer: Yes, antimicrobial agents may be used more than once. However, the antimicrobial agents must be used in accordance with the approved or accepted conditions of use. Labeling is required

unless the use of the substance is consistent with FDA's definition of a processing aid or is a secondary direct food additive.

21. Question: Do all uses of antimicrobial agents need to comply with the requirements of 9 CFR 441.10 for retained water? What are the requirements?

Answer: Yes, any establishment that uses a post-evisceration process that results in water retention in raw livestock or poultry carcasses or parts must maintain on file a written data collection protocol in accordance with 9 CFR 441.10 (c) (1). Any treatment in the chilling process such as antimicrobial treatments should be described in the protocol. An establishment does not have to maintain a protocol on file if it has data or information that clearly demonstrates that its products do not retain water as a result of the process, e.g., spraying boneless meat with antimicrobial agents where the end product does not retain water from the antimicrobial application (FSIS Directive 6700.1).

**United States Department of Agriculture
Food Safety and Inspection Service
Printing Management Section, ASD
5601 Sunnyside Avenue, Mail Drop 5241
Beltsville, MD 20705-5241**

**OFFICIAL BUSINESS
Penalty for Private Use, \$300**

**FIRST-CLASS MAIL
POSTAGE & FEES PAID
USDA-FSIS
Permit No. G-42**

CHANGE TRANSMITTAL SHEET

☐ DIRECTIVE
☐ REVISION
☒ AMENDMENTS
☐ OTHER

FSIS Directive
Food Labeling Division
Policy Memoranda

7220.1
Rev. 2
Amend. 13
1-27-93

I. PURPOSE

This document transmits seven policy memoranda, Amendment 13, to FSIS Directive 7220.1, Revision 2, dated August 24, 1988, due to publication of final nutrition labeling regulations on January 6, 1993. This regulation is effective on July 6, 1994.

II. CHANGES

A. Insert the following policy memoranda in numerical order in Attachment 1 of FSIS Directive 7220.1, Revision 2.

Policy Memo No.	Date
046A	January 6, 1993
049D	January 6, 1993
070C	January 6, 1993
071B	January 6, 1993
078A	January 6, 1993
086A	January 6, 1993
121A	January 6, 1993

B. The following policy memoranda are in effect during the interim period of January 6, 1993, through July 6, 1994, but will be **rescinded** July 6, 1994. Except for Policy Memorandum 121A, the policy memoranda listed in II., A., above will also be **rescinded** July 6, 1994 (See Attachment).

Policy Memo No.	Date
007	August 20, 1980
039	January 18, 1982

C. The following policy memoranda are in effect during the interim period of January 6, 1993, through July 6, 1994, but will be **revised** July 6, 1994 (See Attachment).

Policy Memo No.

Date

016A	March 27, 1981
019A	May 4, 1987
069	March 23, 1984
114	July 6, 1988
121A	January 6, 1993

III. POLICY

A. Companies desiring to continue declaring nutrition-related information on labels in accordance with existing policy memoranda may do so until July 6, 1994.

B. During the interim period, labels must conform either to policies established in the cited policy memoranda or the new regulations, but not both. No combinations will be allowed.

IV. CANCELLATION

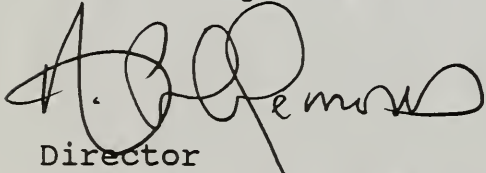
A. The following policy memoranda are cancelled and should be **removed** (See Attachment).

Policy Memo No.

Date

074A	November 4, 1986
085B	January 26, 1988

B. This change transmittal is cancelled when contents have been incorporated into FSIS Directive 7220.1, Revision 2.


Director
Food Labeling Division
Regulatory Programs

Attachments

**CHANGES AS A RESULT OF THE
NUTRITION LABELING REGULATIONS**

Rescind Now	Follow Until July 6, 1994*	Follow Until July 6, 1994**
074A	007	016A
085B	039	019A
	049D	114
	049D	121A
	070C	069
	070C	
	078A	
	086A	
	121A	

* These policy memoranda will be rescinded on July 6, 1994.

** These policy memoranda will be revised on July 6, 1994.

THE UNIVERSITY OF CHICAGO

DEPARTMENT OF CHEMISTRY

EXPERIMENTAL DATA	
1. Name of compound	
2. Molecular weight	
3. Boiling point	
4. Melting point	
5. Density	
6. Refractive index	
7. Solubility	
8. Other properties	

ANALYSIS



6 JAN 1993

To: Branch Chiefs, FLD

Policy Memo 046A

From: Ashland L. Clemons, Director
Food Labeling Division
Regulatory Programs

Subject: Percent Fat Free Label Declarations

ISSUE: Requirements for the approval of percent fat free declarations.

POLICY: This policy memo replaces Policy Memo 046. Percent fat free statements, e.g., "95% Fat Free," are acceptable on product labels if the labels also bear a positive declaration of the product's fat content, e.g., "contains 5% fat." This percent fat statement should be contiguous to the percent fat free statement and be displayed in a prominent manner.

The percent fat free statement and the accompanying statement of the fat content are considered representations of the fat content of the product only and do not necessarily represent the fat free portion as lean material. Thus, concomitant claims of the lean content, such as "95% Lean," will be closely scrutinized.

RATIONALE: These guidelines are issued to identify the policy the meat and poultry industry may use for the labeling of percent fat free information during the period between the promulgation of the nutrition labeling regulations (January 6, 1993) and its implementation date (July 6, 1994). The guidelines essentially reflect policy that has been applied to percent fat free labeling for a number of years, with the exception that the requirements for data submission at the time of label approval and the need for a Nutrition Labeling Verification procedure or Partial Quality Control program have been deleted. The Agency believes that it is necessary to remove these requirements so that the industry may devote existing resources to the development of the nutritional information needed to comply with the new nutrition labeling regulations.

10/10/10

10/10/10

10/10/10

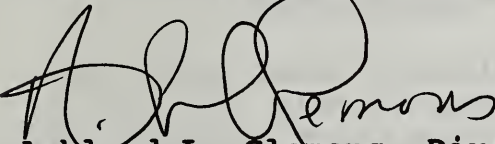
10/10/10



6 JAN 1993

To: Branch Chiefs, FLD

Policy Memo 049D


From: Ashland L. Clemons, Director
Food Labeling Division
Regulatory Programs

Subject: Sodium Labeling Guidelines

ISSUE: What guidelines should be followed in the review and approval of labeling which includes sodium and/or salt information?

POLICY: This policy memo replaces Policy Memo 049C.

1. The label of any meat or poultry product may bear quantitative information on the amount of sodium in a serving of the product. When this information is provided, the serving size must appear on the label and must be within the range of serving sizes customarily used for that product. Sodium content information may be included without other nutrition information.
2. Quantitative information on sodium content shall be declared in terms of milligrams (mg) per serving of the product. The sodium content shall be expressed as zero when the serving contains less than 5 mg, to the nearest 5 mg increment when the serving contains 5 to 140 mg of sodium, and to the nearest 10 mg increment when the serving contains greater than 140 mg of sodium.
3. Nutrition labeling does not require the inclusion of sodium content information. However, if sodium content information is included on the nutrition information panel of a meat or poultry product, the sodium content information must immediately follow the information on fat content (or, if provided, any information on fatty acid and/or cholesterol content).
4. When a claim is made about the sodium and/or salt content of a product, the label of the product must bear quantitative information on the sodium content in a serving of the product.
5. "Very Low Sodium" may be applied only to products that contain 35 mg or less of sodium per serving. "Low Sodium" may be applied only to products that contain 140 mg or less

of sodium per serving. "Sodium Free" and similar terms may be applied only to products that contain less than 5 mg of sodium per serving. "Salt Free" and similar terms may be applied only to products that qualify to be labeled "Sodium Free."

6. "Unsalted" or "No Salt Added" or "Without Added Salt" or an equivalent term may be applied to products only if: (1) no salt is added during processing and no ingredient contains salt (sodium chloride), and (2) the product that it resembles and for which it substitutes is normally processed with salt.

7. "Reduced Sodium" may be applied only to those products which have been formulated to serve as and are represented as direct replacements for foods containing at least four times the sodium content (75 percent reduction). The label of the product shall provide quantitative information comparing the sodium content per serving of the reduced product with that of an equivalent serving of the product it replaces. This information should be in immediate conjunction with the claim or referenced by an asterisk.

8. A comparative sodium content claim may not be made unless: (1) a product's sodium content is at least 25 percent less than that of the appropriate product(s) with which it is compared, and (2) the comparative claim is accompanied by (in immediate conjunction with the claim or referenced by an asterisk) an identification of the product(s) with which the comparison is being made and a quantitative statement of the relative or absolute difference in sodium content per serving (using equivalent serving sizes) of the product(s) being compared. Examples of such claims would be "This bologna has 25% less sodium per serving than our regular bologna," or "This bologna contains 125 mg less sodium per serving than the three leading brands of bologna." While a 25 percent reduction in sodium is necessary in order to make such comparative claims, companies are encouraged to decrease the sodium content of their products in lesser amounts and, if necessary, incrementally as experience is gathered.

RATIONALE: These guidelines are issued to identify the policy the meat and poultry industry may use for the labeling of sodium information during the period between the promulgation of the nutrition labeling regulations (January 6, 1993) and its implementation date (July 6, 1994). The guidelines essentially reflect the policy that has been applied to sodium information labeling for a number of years, with the exception that the requirements for data submission at the time of label approval and the need for a Nutrition Labeling Verification procedure or Partial Quality Control program have been deleted. The Agency believes that it is necessary to remove these requirements so

that the industry may devote existing resources to the development of the nutritional information needed to comply with the new nutrition labeling regulations.



6 JAN 1993

To: Branch Chiefs, FLD

Policy Memo 070C

From: Ashland L. Clemons, Director
Food Labeling Division
Regulatory Programs

Subject: Fat and Lean Claims

ISSUE: What are the guidelines for the review and approval of labeling claims relating to the fat and lean content of meat and poultry products?

POLICY: This policy memo replaces Policy Memo 070B. Emphatic expressions of the lean content of a meat or poultry product, e.g., "lean," "extra lean," and "low fat," and comparative expressions of lean or fat content, e.g., "leaner," "lower fat," "less fat," may be used in the labeling of meat and poultry products.

"Low Fat" may be used only for those products that contain no more than 10 percent fat. "Lean" may be used only for those products that contain no more than 10 percent fat except for ground beef and hamburger. "Extra lean" may be used only for those products that contain no more than 5 percent fat except for ground beef and hamburger. In each case, the actual amount of fat in the product must be disclosed, e.g., "contains 4 percent fat" and either accompany the claim or be referenced by means of an asterisk and placed elsewhere on the principal display panel, on the information panel, or be included as a part of other nutrition information.

When ground beef and hamburger are labeled as "lean" or "extra lean," they must have at least a 25 percent reduction in fat from the regulatory standard of 30 percent fat (i.e., they can contain no more than 22.5 percent fat). In each case, the actual fat percentage and the lean percentage must either accompany the claim or be referenced by means of an asterisk and placed elsewhere on the principal display panel. For example, 20 percent fat ground beef could be labeled "Lean Ground Beef, Contains 80 percent Lean and 20 percent Fat." Ground beef or hamburger, not labeled as "lean" or "extra lean," may continue to be labeled with a fat percentage (i.e., Contains 20 percent Fat). However, ground beef and hamburger may not be labeled

with only a lean percentage. A fat percentage must accompany any claim about the lean content. In all cases, the fat percentage must be in lettering of the same size, type, and on the same background as the lean percentage.

Comparative expressions of the lean or fat content of products may be used only if there is at least a 25 percent reduction or difference in fat or lean content from (1) the amount of fat permitted by an applicable standard if the amount of fat identified by the standard is representative of the majority of the products in the marketplace, e.g., a comparison to the pork sausage standard would not be permitted because market-basket surveys have shown that the average fat content of pork sausage is approximately 40 percent and not close to the 50 percent fat allowed by the standard, (2) the amount of fat in a market-basket survey of comparable products, or (3) the amount of fat in a similar product or class of products as found in recent applicable references such as the revised editions of Composition of Foods - Agriculture Handbook No. 8. An explanation that includes quantitative information about the fat or lean content of the lower fat product and a comparison of its fat or lean content to any of the above references must also be included on the labeling. For example, the explanation for a product labeled "Leaner Italian Sausage" might be "This product contains 24 percent fat, which is 30 percent less fat than allowed by the USDA standard for Italian Sausage."

Fanciful names, brand names, and trademarks often include lean terms. In the case of frozen dinners and entrees, the terms are assumed to represent these products as useful in the reduction or maintenance of body weight. An example is "Lean Cuisine." When such terms are used for this purpose, the products must be nutritionally labeled in accordance with Policy Memo 039. In other situations where the terms are included in fanciful names, brand names, and trademarks to convey the leanness of a product or a substantial reduction in fat, the explanation for comparative expressions of lean or fat content described therein is required unless the products meet the definitions for "lean," "extra lean," or "low fat."

All products with claims about the lean content will be closely examined to assure that the products became leaner due to the replacement of fat by lean material, i.e., indigenous meat or poultry protein and the natural moisture associated with the protein. In situations where a fat content declaration would not accurately reflect the lean content of the product, a statement that discloses the actual amount of lean material in the leaner product expressed as the percent lean material or percent protein may be needed, e.g., "50 percent leaner than average _____ -- contains 25 percent protein." These statements may accompany the claim or be referenced by means of

an asterisk and placed elsewhere on the principal display panel or on the information panel.

Generally, the emphatic claims "lean" and "extra lean" will be limited to products composed solely of fat and lean material with no added substances such as water or extenders. In those limited situations where it can be demonstrated that the product before and after the addition of any added substances contained no more than 10 percent or 5 percent fat, as the case may be, the emphatic claims may be used. For example, a ham and water product could not be labeled "lean" if it contained 10 percent fat, since the product became lean by dilution with water and other added substances. However, if the meat portion contained no more than 10 percent fat before processing, the product could be labeled "lean."

The policy of allowing on the labeling of whole cuts or parts of meat or poultry terms such as "lean" and "extra lean" if stated in the possessive and accompanied by a guarantee statement has been withdrawn. These products must meet the definitions for use of these terms. Comparative terms, e.g., "leaner," "lower fat," etc., may be used if there is at least a 25 percent decrease in fat or increase in lean content of the product. In this case, a comparative explanation as described above is required.

The terms "lean," "50/50," and other similar designations which are used as meat industry trade terms to designate the leanness of meat for further processing are acceptable without an explanation as required by this policy memo. However, when the lean or fat content is expressed as a true percentage, the company must either add contiguous to the product name the phrase, "For Further Processing," or some similar designation that indicates the product is to be further processed.

RATIONALE: These guidelines are issued to identify the policy the meat and poultry industry may use for the labeling of fat and lean claims during the period between the promulgation of the nutrition labeling regulations (January 6, 1993) and its implementation date (July 6, 1994). The guidelines essentially reflect the policy that has been applied to fat and lean claims for a number of years, with the exception that the requirements for data submission at the time of label approval and the need for a Nutrition Labeling Verification procedure or Partial Quality Control program have been deleted. The Agency believes that it is necessary to remove these requirements so that the industry may devote existing resources to the development of the nutritional information needed to comply with the new nutrition labeling regulations.

Labeling claims concerning a product's fat or lean content can be informative and useful to consumers in making food choices. Processors producing products with reduced amounts of fat or using leaner meat or poultry ingredients should be able to label their products to indicate this characteristic. A claim alone without some explanation of its meaning may be misleading and, in most cases, does not provide the information necessary to make a value judgment. The explanation accompanying most claims must be designed to enable the consumer to make a comparison. In some cases, a disclosure of only the fat or lean content will provide the necessary information.

Definitions are being established for "lean" and "extra lean" (except for ground beef and hamburger) as well as "low fat" since they are absolute terms which have taken on increasing importance to the consumer in recent years. "Lean" and "low fat" are comparable in meaning and are given the same definition. "Extra lean" is given a more strict definition because consumers would expect a product so labeled to have less fat than a product labeled "lean" or "low fat."

Because of the history of successful State and local regulation of the meaning of "lean" and "extra lean" ground beef and hamburger, the absolute definitions established are not considered necessary. The State and local requirements do vary, but by stating the fat and lean content of the product, such labeling will assure that consumers do not mistakenly believe that "lean ground beef" contains no more than 10 percent fat.

The policy allowing only a reduction to 25 percent fat (a 17 percent reduction) for products that may contain no more than 30 percent fat has been withdrawn. It was recognized that this was an anomaly and it is preferable to be consistent with other policies both within this Agency and the Food and Drug Administration that require a 25 percent reduction in some component before a claim can be made.

The longstanding policy of allowing the use of fat and lean claims if stated in the possessive and accompanied by a guarantee statement has been withdrawn. The widespread interest in fat and its relation to diet demands that quantitative information be available to the consumer. Furthermore, the policy had only limited application, and it is important to have a consistent approach for all products in order to avoid confusion and promote consumer understanding.

The comparisons to leading brands, a leading brand, or the company's regular product are not being permitted in the interest of eliminating comparisons that have limited value. In some cases, the leading brand or regular product was not marketed in the same areas as the "leaner" or "lower fat"

product and these comparisons were of limited value to consumers. Also, the leading brand or regular product comparisons provide information which often is not representative of most products in the marketplace.

The term "Lean," when used by industry to describe red meat should not be confused with other uses outlined in this policy memo. We have recognized that this usage of lean is very common among industry and is instrumental as both an inhouse means of identifying product and as a way to describe product shipped to other plants to be further processed into a formulated product. Indicating fat and lean by use of a ratio (e.g., 50/50) is also a practice which has been used by industry for years. We have always regarded this as an estimate of the amount of lean material, and have never imposed the requirements of supportive data or quality control.

Percent labeling of an ingredient or component will no longer require implementation of a quality control program to assure ongoing accuracy of the label information. However, addition of a qualifier showing that the product is to be used for further processing should satisfy industry's need for the term, while distinguishing it from retail product marketed as "Lean."

The first of these is the fact that the
government has been unable to
obtain the necessary funds to
carry out its policy. This is due
to the fact that the government
has been unable to raise the
necessary funds to carry out its
policy. This is due to the fact
that the government has been
unable to raise the necessary
funds to carry out its policy.

The second of these is the fact that
the government has been unable to
obtain the necessary funds to
carry out its policy. This is due
to the fact that the government
has been unable to raise the
necessary funds to carry out its
policy. This is due to the fact
that the government has been
unable to raise the necessary
funds to carry out its policy.



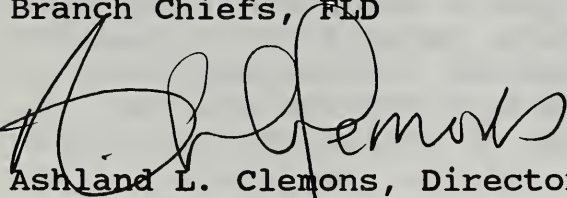
6 JAN 1993

To:

Branch Chiefs, FLD

Policy Memo 071B

From:


Ashland L. Clemons, Director
Food Labeling Division
Regulatory Programs

Subject:

Lite and Similar Terms

ISSUE: What are the guidelines for the review and approval of labeling terms such as "Lite," "Light," "Lightly," and similar terms?

POLICY: This policy memo replaces Policy Memo 071A. Terms such as "Lite," "Light," "Lightly" may be used on the labels of meat and poultry products. Such terms generally imply that a product has significantly fewer calories than expected in a similar product but often are used to relate that a product has significantly less fat, salt, sodium, breeding and/or other components than a similar product. A significant reduction is considered to be at least 25 percent. In the case of a salt reduction, the sodium content must also be reduced by at least 25 percent (see Policy Memo 049D).

If used, the terms generally must be explained either adjacent to the term or referenced by means of an asterisk and placed elsewhere on the principal display panel or on the information panel. The explanation must provide to the purchaser quantitative information about the amount of calories, fat, salt, sodium and/or other components in the product and include a quantitative comparison to (1) the amounts permitted by an applicable standard if the amount identified by the standard is representative of the majority of the products in the marketplace, e.g., a comparison to the fat content of the pork sausage standard would not be permitted because market-basket surveys have shown that the average fat content of pork sausage is approximately 40 percent and not close to the 50 percent fat allowed by the standard, (2) the amounts found in a market-basket survey of comparable products, or (3) the amounts in a similar product or class of products as found in recent applicable reference sources such as the revised editions of Composition of Foods -- Agriculture Handbook No. 8.

For products that are unquestionably low in calories, fat, salt, breading, or sodium, the explanation required to accompany such terms need only consist of a disclosure of the actual amount in the product. For this purpose, the amount of calories can be no more than 40 calories per serving and no more than 0.4 calories per gram of product. For fat and breading, the product can contain no more than 10 percent. For salt and sodium, the product can contain no more than 35 mg of sodium per 100 grams of product.

Fanciful names, brand names, and trademarks often include lite terms. In the case of frozen dinners and entrees, the terms are assumed to represent these products as useful in the reduction or maintenance of body weight. An example is "Dining Lite." When such terms are used for this purpose, the products must be nutritionally labeled in accordance with Policy Memo 039. In other situations where the terms are included in fanciful names, brand names, and trademarks to convey the leanness of a product or a substantial reduction in fat, the explanation for comparative expressions of fat content described above is required. Those products containing no more than 10 percent fat may provide a declaration of fat content as the explanatory statement.

RATIONALE: These guidelines are issued to identify the policy the meat and poultry industry may use for the labeling of "Lite" and similar terms during the period between the promulgation of the nutrition labeling regulations (January 6, 1993) and its implementation date (July 6, 1994). The guidelines essentially reflect the policy that has been applied to "Lite" and similar terminology for a number of years, with the exception that the requirements for data submission at the time of label approval and the need for a Nutrition Labeling Verification procedure or Partial Quality Control program have been deleted. The Agency believes that it is necessary to remove these requirements so that the industry may devote existing resources to the development of the nutritional information needed to comply with the new nutrition labeling regulations.

Labeling claims that include terms such as "Lite," "Light," "Lightly," and similar terms which imply that a product has reduced levels of various components can be informative and useful to consumers in making food choices. Processors making products with reduced amounts of various components should be able to indicate this characteristic on labeling. A claim alone without some explanation of its meaning may be misleading and certainly does not provide the information necessary for consumers to make informed judgments. The explanation accompanying most claims must be designed to enable the consumer to make a comparison. In some cases where a product is

unquestionably low in various components, a disclosure of only the absolute amount will provide the necessary information.

The policy of allowing a reduction to only 25 percent fat (a 17 percent reduction) for products that may contain no more than 30 percent fat is being withdrawn. It is recognized that this was an anomaly and it is preferable to be consistent with other policies both within this Agency and the Food and Drug Administration that require a 25 percent reduction in some components before a claim may be made.

The comparisons to leading brands, a leading brand, or the company's regular product are no longer being permitted in the interest of eliminating comparisons that have limited value. In some cases, the leading brand or regular product was not marketed in the same areas as the "lite" product and these comparisons were of limited value to consumers. Also, comparisons to the leading brand or regular product provide information which often is not representative of most products in the marketplace.

The first part of the paper is devoted to a discussion of the general principles of the theory of the structure of the atom. It is shown that the structure of the atom is determined by the laws of quantum mechanics, which are based on the principle of the uncertainty of the position and momentum of the particles. The second part of the paper is devoted to a discussion of the structure of the nucleus. It is shown that the structure of the nucleus is determined by the laws of quantum mechanics, which are based on the principle of the uncertainty of the position and momentum of the particles.

The third part of the paper is devoted to a discussion of the structure of the molecule. It is shown that the structure of the molecule is determined by the laws of quantum mechanics, which are based on the principle of the uncertainty of the position and momentum of the particles. The fourth part of the paper is devoted to a discussion of the structure of the crystal. It is shown that the structure of the crystal is determined by the laws of quantum mechanics, which are based on the principle of the uncertainty of the position and momentum of the particles.

The fifth part of the paper is devoted to a discussion of the structure of the liquid. It is shown that the structure of the liquid is determined by the laws of quantum mechanics, which are based on the principle of the uncertainty of the position and momentum of the particles. The sixth part of the paper is devoted to a discussion of the structure of the gas. It is shown that the structure of the gas is determined by the laws of quantum mechanics, which are based on the principle of the uncertainty of the position and momentum of the particles.

The seventh part of the paper is devoted to a discussion of the structure of the plasma. It is shown that the structure of the plasma is determined by the laws of quantum mechanics, which are based on the principle of the uncertainty of the position and momentum of the particles. The eighth part of the paper is devoted to a discussion of the structure of the solid. It is shown that the structure of the solid is determined by the laws of quantum mechanics, which are based on the principle of the uncertainty of the position and momentum of the particles.

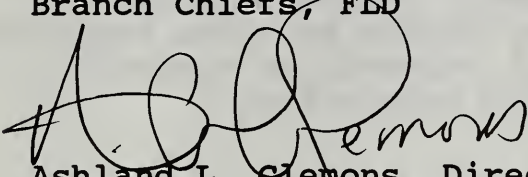
The ninth part of the paper is devoted to a discussion of the structure of the liquid crystal. It is shown that the structure of the liquid crystal is determined by the laws of quantum mechanics, which are based on the principle of the uncertainty of the position and momentum of the particles. The tenth part of the paper is devoted to a discussion of the structure of the polymer. It is shown that the structure of the polymer is determined by the laws of quantum mechanics, which are based on the principle of the uncertainty of the position and momentum of the particles.



6 JAN 1993

To: Branch Chiefs, FLD

Policy Memo 078A

From: 
Ashland L. Clemens, Director
Food Labeling Division
Regulatory Programs

Subject: Potassium Labeling Guidelines

ISSUE: What guidelines should be followed in the review and approval of labeling which includes potassium information?

POLICY: This policy memo replaces Policy Memo 078.

1. The label of any meat or poultry product may bear quantitative information on the amount of potassium in a serving of the product. When this information is provided, the serving size must appear on the label and must be within the range of serving sizes customarily used for that product. Potassium and sodium content information may be included without other nutrition information. Labels may not bear nutrition information on potassium content alone.

2. Quantitative information on potassium content shall be declared in terms of milligrams (mg) per serving of the product. The potassium content shall be expressed as zero when the serving contains less than 5 mg, to the nearest 5 mg increment when the serving contains 5 to 140 mg of potassium, and to the nearest 10 mg increment when the serving contains greater than 140 mg of potassium.

3. Nutrition labeling does not require the inclusion of potassium content information. However, if potassium content information is included on the nutrition information panel of a meat or poultry product, the potassium content information must immediately follow the information on sodium content.

RATIONALE: These guidelines are issued to identify the policy the meat and poultry industry may use for the labeling of potassium information during the period between the promulgation of the nutrition labeling regulations (January 6, 1993) and its implementation date (July 6, 1994). The guidelines essentially reflect the policy that has been applied to potassium information labeling for a number of years, with the exception that the requirements for data submission at the time of label

approval and the need for a Nutrition Labeling Verification procedure or Partial Quality Control program have been deleted. The agency believes that it is necessary to remove these requirements so that the industry may devote existing resources to the development of the nutritional information needed to comply with the new nutrition labeling regulations.



6 JAN 1993

To: Branch Chiefs, FLD

Policy Memo 086A

From: Ashland L. Clemons, Director
Food Labeling Division
Regulatory Programs

Subject: Nutrition Labeling

ISSUE: What are the guidelines for the approval of nutrition labeling on meat and poultry products?

POLICY: This policy memo replaces Policy Memo 086 dealing with nutrition labeling. The following guidelines are currently being used in the review and approval of nutrition label information when it is voluntarily provided by the processor or when it is required due to the presence of labeling claims or features relating to calorie content and weight control (see Policy Memo 039). Nutritional information may appear on the label's principal display panel or information panel (see Policy Memo 007 on uses of the information panel).

Nutrition information may be presented in the format and style provided by FDA regulations prior to recently issued nutrition labeling regulations (see enclosed example). The format includes the following information presented in this order: the size of one serving presented in common household measures or recognized portions such as cups, ounces, slices, pieces, etc.; the number of servings or portions per container; the number of calories per serving/portion, the number of grams of protein, carbohydrates, and fat per serving/portion; and the percent of the U.S. Recommended Daily Allowance (U.S. RDA) of protein, vitamin A, vitamin C, thiamine, riboflavin, niacin, calcium, and iron per serving/portion. Inclusion of the B vitamins (thiamine, riboflavin, and niacin) in the FDA nutrition format is optional for labeling meat and poultry products.

An abbreviated format is also accepted for labeling meat and poultry products. This format includes the number of calories and the number of grams of protein, carbohydrate, and fat in a specified serving or portion of the product and the servings or portions per container.

Both nutrition labeling formats may be supplemented with information on other nutrients that may be of interest to consumers. Examples include: fatty acid composition reported in grams per serving/portion, milligrams of cholesterol reported in 5mg increments and sodium information reported according to the guidelines in Policy Memo 049D. When the FDA nutrition labeling format is used, information on the percent of the U.S. RDA of additional vitamins and minerals, such as vitamin D and vitamin E, may be included. Other means of presenting nutrition information will also be considered.

RATIONALE: On January 6, 1993, the Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) published final regulations setting forth requirements for the mandatory nutrition labeling of most foods under their respective jurisdictions. Among other things, these regulations provide for the voluntary disclosure of the B vitamins (thiamine, riboflavin, and niacin) because public health concerns for deficient intakes of these vitamins have lessened over the last 20 years. Thus, inclusion of these three nutrients in nutrition labeling is not considered necessary to assist consumers in maintaining healthy dietary practices.

FSIS has historically disseminated its nutrition labeling guidelines for meat and poultry products through the issuance of various policy memoranda by its Food Labeling Division (FLD). Policy Memo 086 entitled Nutrition Labeling, which is the subject of this revision, provided for the disclosure of nutrition information in the format and style described in FDA regulations prior to the recent issuance of nutrition labeling regulations for required components. This memorandum also permitted an abbreviated labeling format for the nutrient content of meat and poultry products that included, calories, protein, carbohydrates, fat, and/or sodium. This revision continues this practice until the effective date of the aforementioned final rule, which is July 6, 1994.

The policy memos that relate in whole or in part to nutrition-related information will be rescinded or revised because of this final rule. Policy Memo 074A, dated November 1986, Exemptions from NLV or PQC, and Policy Memo 085B, dated January 1988, NLV Procedures, will no longer be in effect upon promulgation of this final rule. Policy Memo 086, dated May 1985, Nutrition Labeling, Policy Memo 046, dated April 1982, Percent Fat Free Label Declarations, Policy Memo 049C, dated June 1984, Sodium Labeling Guidelines, Policy Memo 070B, dated November 1987, Fat and Lean Claims, Policy Memo 071A, dated March 1986, Lite and Similar Terms, Policy Memo 078, dated November 1984, Potassium Labeling Guidelines, and Policy Memo 121, dated May 1991, Labeling of Low Fat Ground Beef and Low Fat Hamburger Containing Added Ingredients, will remain in effect during the 18-month

period between the date of publication and the effective date of this final rule, except that the provisions relating to data requirements and requirements for an NLV procedure or Partial Quality Control Program will not be enforced. Policy Memo 007, dated August 1980, Information Panel, and Policy Memo 039, dated January 1982, Caloric Claims/Weight Reduction, will remain in effect during the interim period but will be rescinded just before or upon the effective date of this final rule. Policy Memo 016A, dated March 1981, Combinations of Ground Beef or Hamburger and Soy Products, Policy Memo 069, dated March 1984, Labeling for Substitute Products, Policy Memo 019A, dated May 1987, Negative Labeling, and Policy Memo 114, dated July 1988, Point of Purchase Materials, will remain in effect during the interim period but will be revised just before or upon the effective date of this final rule. Thus, companies desiring to continue declaring nutrition-related information on labels in accordance with existing policy memoranda may do so until the effective date, which is July 6, 1994.

Official establishments desiring to continue declaring nutrition-related information on labels in accordance with the above policy memoranda may do so until the effective date of the final nutrition labeling regulation. At or before that time, all of the memoranda listed above will be rescinded or revised and any new labels or other labeling would then be required to conform to the provisions of the final rule. During this interim period, however, labels must conform either to policies established in the above-cited policy memoranda or the new regulations, but not both. In other words, no combinations may be allowed.

Enclosure

Enclosure

Nutrition Information Per Serving/Portion

Serving/Portion Size:
Servings/Portions Per Container:
Calories:
Protein:
Carbohydrate:
Fat:
Sodium:

Percentage of U.S. Recommended
Daily Allowance (U.S. RDA)

Protein	Riboflavin (optional)
Vitamin A	Niacin (optional)
Vitamin C	Calcium
Thiamine (optional)	Iron



6 JAN 1993

To: Branch Chiefs, FLD

Policy Memo 121A

From: Ashland L. Clemons, Director
Food Labeling Division
Regulatory Programs

Subject: Labeling of Low Fat Ground Beef and Low Fat
Hamburger Containing Added Ingredients

ISSUE: How should low fat products which substitute for ground beef and hamburger be labeled, and what other requirements are necessary to obtain label approval and use of final labels?

POLICY: This policy memo replaces Policy Memo 121.

Low fat products which combine hamburger or ground beef and other nonfat ingredients may be descriptively labeled, e.g., "Low Fat Ground Beef With a X% Solution of ..." or "Low Fat Hamburger, Water, and Carrageenan Product." A combination product which is not low fat is to be labeled as Imitation Ground Beef (or Hamburger) or Beef Patty or Beef Patty Mix in accordance with 9 CFR Section 317.2(j)(1) and Section 319.15(c), respectively. Descriptively labeled low fat combination products should comply with the following guidelines:

- (1) The finished product may contain no more than 30 percent of a combination of fat and added substances and no more than 10 percent fat.
- (2) The product includes nutrition labeling that provides, at a minimum, serving (portion) size, servings (portions) per container (if appropriate), total calories, calories from fat, protein, carbohydrates, total fat, saturated fat, and sodium.
- (3) Words in the descriptive name may be of a different size, style, color, or type but, in all cases, the words must be prominent, conspicuous, and legible. Moreover, no word in the descriptive name should be printed in letters that are less than one-third the size of the largest letter used in any other word in the descriptive name. The solution statement, when used, is considered to be part of the descriptive product name and must comply with descriptive name sizing requirements.

(4) If percentage labeling is included as part of the product name, e.g., "Low Fat Ground Beef With a X% Solution of ...," a Partial Quality Control (PQC) program for the addition of solutions must be approved before the label can be used.

RATIONALE: These guidelines are issued to identify the policy the meat and poultry industry may use for the labeling of low fat ground beef products containing added ingredients during the period between the promulgation of the nutrition labeling regulations (January 6, 1993) and its implementation date (July 6, 1994). The guidelines essentially reflect the policy that has been applied to the labeling of low fat ground beef products containing added ingredients for a number of years, with the exception that the requirements for data submission at the time of label approval and the need for a Nutrition Labeling Verification procedure have been deleted. The Agency believes that it is necessary to remove these requirements so that the industry may devote existing resources to the development of the nutritional information needed to comply with the new nutrition labeling regulations.

This policy allows flexibility in developing and marketing low fat products that may be substituted for ground beef and hamburger while maintaining the product's nutritional quality. The policy provides labeling that informs the public of the actual characteristics of the products and is in keeping with the Department's policy on descriptive labeling. Since the combination foods differ from regular hamburger and ground beef with regard to moisture content and fat content, it is important that nutrition information be included with labeling so that the consumer can make better comparative nutritional judgments.

This policy memo provides further guidance for compliance with Section 317.2(b). The intent of this policy is consistent with Policy Memo 087A regarding word size in labeling of product names.

The need for a Partial Quality Control program is consistent with the Department's policy regarding percentage labeling.

The policy permits the use of added nonfat ingredients as fat replacement.



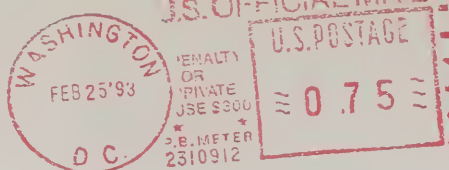
United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C.
20250

OFFICIAL BUSINESS

Penalty for Private Use, \$300



FIRST CLASS MAIL

37/483MPSLD1594 R1 103-0001
E3

US DEPT OF AGRICULTURE
FOOD & NUTRI INFORMATION CNTR
NAT'L AGRI LIBRARY, RM 304
BELTSVILLE MD 20705-2351

FSIS DIRECTIVE

7237.1

2-22-94

LABELING OF INGREDIENTS

I. PURPOSE

The purposes of this directive are to:

A. prescribe FSIS' policy on ingredient labeling when FDA-standardized foods, FDA-certified color additives, or protein hydrolysates are used as ingredients in meat and poultry products,

B. give official establishments the opportunity to make changes when designing new labels, and

C. serve as a guide for use with applicable parts of the MPI Regulations.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

MPI Regulations, Parts 317, 318, 319, and 381

FDA Regulations, 21 CFR, Parts 73, 74, 101, 102, 130, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 166, 168, and 169

V. DEFINITIONS

FDA	Food and Drug Administration
MPI	Meat and Poultry Inspection

VI. POLICY/BACKGROUND

A. FSIS regulates the labeling of meat and poultry products while FDA has responsibility for all other food labeling. When FDA-regulated foods and food ingredients are used as components and ingredients in meat and poultry products, FSIS generally follows FDA's requirements for ingredient labeling of those foods and ingredients.

B. On January 6, 1993, FDA published regulations amending its ingredient labeling requirements for standardized foods, color additives, and protein hydrolysates. FDA amended the regulations in response to the Nutrition Labeling and Education Act of 1990. The amended regulations require the listing of the common or usual names of all ingredients in standardized foods and all FDA-certified color additives. The regulations also require the listing of the common and usual names of protein hydrolysates and the identity of the source from which the protein was derived. FDA's regulations will become effective May 8, 1994.

C. FSIS' policy regarding the labeling of FDA-standardized foods, FDA-certified color additives and protein hydrolysates, when used as components or ingredients in meat and poultry products, will parallel FDA's regulatory changes as published on January 6, 1993. FSIS will begin enforcing this policy on July 6, 1994, which is the effective date for compliance with the nutrition labeling regulations. Changes to the MPI Regulations resulting from this policy, (i.e., changing the common or usual name of hydrolyzed milk protein whenever it appears), will be published in the Federal Register.

VII. LABELING OF INGREDIENTS

A. When FDA-standardized foods, FDA-certified color additives, or protein hydrolysates are used as ingredients in meat and poultry products, they must be labeled in accordance with the following requirements:

1. Ingredients of FDA Regulated Standardized Foods.

When FDA standardized foods are used as ingredients in the preparation of meat or poultry products, the common or usual names of all ingredients in the FDA standardized foods must be properly shown. For example, when cheddar cheese is used as an ingredient in meat or poultry products, it would be declared as "cheddar cheese ()," with the blank space filled in with the common or usual names of all ingredients of the cheddar

cheese. An alternate method would be to incorporate all ingredients of a standardized food in their order of predominance in the ingredients statement of the finished product without naming the standardized food.

2. Label Declaration of Color Additives. A color additive or the lake of a color additive subject to FDA certification must be declared by its common or usual name or the abbreviated name such as "FD&C Red No. 40," "Red 40," "FD&C Blue No. 1 Lake," or "Blue 1 Lake." Color additives not subject to certification may be declared as "Artificial Color," "Artificial Color Added," or "Color Added." Alternatively, such color additives may be declared as "Colored with _____," or "_____ color," with the blank space filled in with the name of the color additive listed in 21 CFR 73, e.g., colored with annatto or caramel color.

3. Source Labeling and the Degree of Hydrolysis of Protein Hydrolysates. The common or usual names of a protein hydrolysate should be specific to the ingredient and shall include the identity of the source from which the protein was derived. "Hydrolyzed casein" and "autolyzed yeast extract" are examples of acceptable names. Generic terms such as "hydrolyzed vegetable protein," "hydrolyzed plant protein," or "hydrolyzed milk protein," are no longer acceptable designations for protein hydrolysates. The degree of hydrolysis will determine the common or usual names of protein hydrolysates. Protein hydrolysates are designated as "hydrolyzed" or "lightly hydrolyzed."

B. All labels which are affected by the above requirements must be submitted to the Food Labeling Division, Regulatory Programs, for review and approval. Manufacturers are encouraged to familiarize themselves with the ingredient labeling procedures and may begin to submit their new labels in accordance with the labeling ingredient requirement.

VIII. FURTHER GUIDANCE

If there are questions concerning this directive, please contact the Branch Chief, Food Standards and Ingredients Branch, Product Assessment Division, Regulatory Programs, at (202) 254-2588.



Deputy Administrator
Regulatory Programs

FSIS DIRECTIVE

7260.1

7-29-93

QUESTIONS AND ANSWERS - NUTRITION LABELING OF MEAT AND POULTRY PRODUCTS

I. PURPOSE

This directive provides an attachment of commonly asked questions and answers in response to the final rule titled "Nutrition Labeling of Meat and Poultry Products" which was published in the Federal Register on January 6, 1993. The final rule is effective on July 6, 1994. This is the first set of questions and answers on this subject and covers the mandatory and voluntary programs, exemptions, nutrients, and formats. Additional questions and answers on serving sizes, nutrient content claims, and compliance and database issues will follow.

II. [RESERVED]

III. [RESERVED]

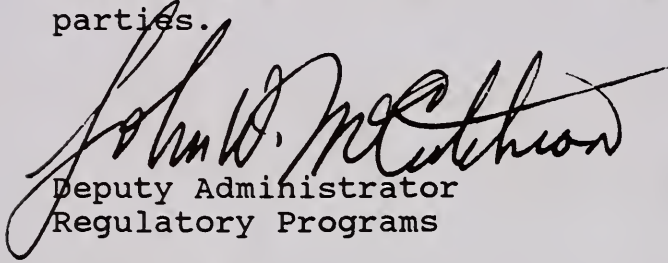
IV. REFERENCES

MPI Regulations, Sections 317.3, 320.1, 381.175, and 381.4;
FDA Regulations, 21 CFR 101;
FSIS Directive 7220.1, Rev. 2, Amend. 13, Policy Memoranda, dated 1/27/93; and
FSIS Notice 4-93, dated 2/9/93

V. POLICY

It is FSIS's policy to provide additional information whenever a complex and/or significant regulation is published. The nutrition labeling regulations substantially affect the manner in which most meat and poultry products are labeled. The attached set of questions and answers is issued to assist manufacturers of

these products to meet the requirements of the regulations and to disseminate information to FSIS employees and other interested parties.



Deputy Administrator
Regulatory Programs

Attachment

QUESTIONS AND ANSWERS - NUTRITION LABELING OF
MEAT AND POULTRY PRODUCTS

QUESTIONS AND ANSWERS - NUTRITION LABELING OF
MEAT AND POULTRY PRODUCTS

TABLE OF CONTENTS

SUBJECT	PAGE NO.
I. MANDATORY AND VOLUNTARY PROGRAMS.....	5
II. EXEMPTIONS.....	11
III. NUTRIENTS.....	17
IV. FORMATS.....	19

**QUESTIONS AND ANSWERS ON NUTRITION LABELING
OF MEAT AND POULTRY PRODUCTS**

I. MANDATORY AND VOLUNTARY PROGRAMS

1. **Question:** Does the implementation date of July 6, 1994, require that all product produced on and after that date comply with the regulations, or does it require that all product in the market on and after that date comply?

Answer: Neither. Compliance with the implementation date is not defined in terms of the time at which product is manufactured or shipped into commerce. It is defined as the time at which product is labeled so that labels applied to products on and after July 6, 1994, must conform to the requirements of the regulations.

2. **Question:** In the case of domestic product, who has the responsibility for ensuring that product is properly labeled, e.g., the producing establishment whose number appears on the label; the company listed on the address line on a label; a firm which co-packs for a different firm; or, a firm which repacks product originated at another company?

Answer: The official, inspected establishment whose number appears on the label is responsible for properly labeling the product. However, multi-plant companies may maintain the records supporting the labels at the headquarter's office from which the labels are often generated.

3. **Question:** How is imported product affected by the regulations?

Answer: Imported product is subject to the identical requirements as domestic product.

4. **Question:** In the case of imported product, is the exporter or the importer responsible for ensuring that the product is properly labeled?

Answer: The foreign facilities permitted to export to the U.S. and producing the product are responsible for proper labeling unless the importer reprocesses or repackages the product under official inspection, whereupon the importer becomes responsible.

5. **Question:** How should information be presented on nutrition labels between January 6, 1993 and July 6, 1994?

Answer: The nutrition information may be presented in format and content to conform either to the new regulations or to existing policy. A combination of the two approaches is not allowed. [The inclusion of thiamin, riboflavin, and niacin is now optional under both approaches.]

6. **Question:** Do previously approved labels need to be resubmitted for prior label approval if only a nutrition panel is added to the label and it is not part of the principal display panel?

Answer: Yes. See the answer to the following question.

7. **Question:** What will be the approval process during the interim period for labels with nutrition information?

Answer: The only change to the process is that the requirement for submission of analytical data at time of label approval and need for a Nutrition Labeling Verification procedure or Partial Quality Control program are removed. Official establishments are encouraged to submit one label application for a product produced in multiple plants under the same ownership when the products have identical formulations, although package sizes may vary and each label must bear the appropriate establishment number before use. Official establishments using labels for products of identical formulation that represent different brand names may also submit one label application for approval with a separate written request listing each such label, date of previous approval, and approval number for each. Further details on procedures are contained in FSIS Notice 4-93 dated 2/9/93.

8. **Question:** Does FSIS have official label approval services for products of foreign countries being exported to the U.S. and, if not, where can companies get their labels checked?

Answer: All such labels must be prior approved by the Food Labeling Division, Regulatory Programs.

9. **Question:** Is ground beef only containing beef a processed product and subject to mandatory labeling or is it considered a single-ingredient beef cut?

Answer: Ground beef, which is not seasoned, is a single-ingredient, raw product falling under the voluntary labeling program. Any product which does not require ingredient labeling and which is not subjected to a processing procedure that would significantly alter nutrient content,

such as thermal processing, qualifies for the voluntary labeling category even when the product has been subjected to mechanical treatments such as slicing and chopping.

10. **Question:** The regulations state that single-ingredient, raw products under the voluntary program include those that have been previously frozen. Does this mean that products sold frozen, as opposed to thawed, are under the mandatory labeling program?

Answer: No. Both frozen and previously frozen products are under the voluntary program. FSIS does not believe that freezing is a processing procedure that would significantly alter nutrient content.

11. **Question:** Under the guidelines for the voluntary program, the regulations refer to a retailer providing information on labels of single-ingredient, raw products without referring to a manufacturer. Does this mean that FSIS makes a distinction between these products when packed and labeled at official establishments and at the retail level?

Answer: No. The term "retailer" as used in this context includes a manufacturer. FSIS makes no distinction between these products when packed and labeled at official establishments, as is typical of poultry products, and those packed and labeled at retail, as generally occurs with most meat products. The site where the product is packed and labeled has no relevance to its inclusion in or exclusion from the voluntary program.

12. **Question:** Can a claim be made on a shipping container, e.g., "our low fat chicken breast," without nutrition labeling the shipping container?

Answer: Yes. However, the packaged product within the shipping container must be nutrition labeled because a claim is made about the product.

13. **Question:** If a nutrition claim is made on a product destined for food service, e.g., a case of 8-piece hams, can the nutritional information be printed on an informational insert for placement in the case with the product?

Answer: Yes. The insert is considered to be labeling and is an appropriate vehicle for transmitting the nutrition information for products destined for food service.

14. **Question:** Would you label a cured ham that comes with a glaze package with one or two labels?

Answer: Either is acceptable. The entire packaged product is an assortment of foods presented to be consumed together, and the nutrient content may be expressed for each individual product or for the entire package contents. If nutrient profiles are given for each product on the outer container of the entire packaged product, they may be presented in two columns in the same "Nutrition Facts" display. The profile for the combination of ham plus glaze could be given additionally in a separate "Nutrition Facts" display or as the sole display on the outer container. The reference amount customarily consumed (RACC) for the combination is the sum of the RACCs for the ham (85 g) and the glaze (amount to make 1/4 cup if not prepared for use).

15. **Question:** If a package contains a single-ingredient, raw product, e.g., a turkey breast, as well as a gravy packet, is the product under the mandatory program and how should it be labeled?

Answer: The product represents two separately packaged foods that are packaged and presented to be consumed together and, as such, is under the mandatory program. As with the preceding ham and glaze example, the manufacturer has the option to label each food individually or the entire contents of the package. If the raw turkey breast is labeled individually, it would be labeled "as packaged," i.e., raw, in this case, and may also be labeled "as consumed," i.e., cooked. Also, the nutrient profile for the gravy mix must be given for the dry mix and may be shown optionally on an "as prepared," i.e., reconstituted, basis. If the manufacturer chooses to label the combination in a "Nutrition Facts" panel on the outer container of the entire package, one column would be used to show a single set of values for the raw breast and dry gravy mix, and a second column could be used to show a single set of values for the cooked breast with prepared gravy.

16. **Question:** What are the definitions of "as packaged," "as consumed," and "as prepared"?

Answer: "As packaged" refers to the state of the product as it is marketed for purchase. "As consumed" and "as prepared" are synonymous terms, but FSIS applies "as consumed" to raw meat and poultry products (i.e., those that are purchased ready-to-cook) after they have been cooked. FSIS uses "as prepared" to describe foods sold fully cooked or that require only minimal preparation (i.e., those that are ready-to-eat or heat-and-serve) after they have been

prepared for consumption, e.g., condensed soup or dry gravy mix that has been reconstituted.

17. **Question:** Can manufacturers label packages of whole turkeys without including the neck and giblets in the nutrition profile when the products are basted and fall under the mandatory program?

Answer: Yes. FSIS believes consumers frequently do not consume these items or eat them as part of the whole bird. Because the neck and giblets are tissues in the package, a footnote should be used to indicate that values exclude neck and giblets when this is the case.

18. **Question:** If a recipe is placed on the label of a product, does the nutritional profile of the recipe have to be included on the label?

Answer: No. Such information would not be included in the nutrition panel except when a product is commonly combined with other ingredients before eating, such as dry soup mix prepared with milk.

19. **Question:** Are labels for game meat slaughtered and processed under voluntary inspection and receiving either the Federal Triangle Brand or an official State Meat Inspection Program brand subject to FSIS or FDA requirements for nutrition labeling and exemptions?

Answer: FDA is responsible for the regulation of all meats not covered by USDA under the Federal Meat and Poultry Products Inspection Acts and has determined that labeling of game meats (e.g., deer, bison, rabbit, wild turkey, or ostrich) is mandatory. The products are subject to FDA requirements for nutrition labeling and exemptions regardless of receiving treatment as described above.

20. **Question:** What are the labeling requirements for product consisting of primarily game meat, but containing more than three percent raw meat from amenable species?

Answer: The product is subject to FSIS requirements for the mandatory labeling program.

21. **Question:** When are point-of-purchase (p-o-p) materials considered labeling?

Answer: They are labeling when they accompany the product for display at the point of purchase or the manufacturer causes them to be present where the product is sold.

22. **Question:** Will p-o-p materials that are not considered labeling be used in measuring significant participation in the voluntary program?

Answer: Yes. Labels applied to products and all p-o-p materials which meet the guidelines for the voluntary program will be used to measure participation.

23. **Question:** What requirements of the mandatory labeling program must be met by manufacturers of products falling into the voluntary category if they elect to 1) label the package, 2) use p-o-p material, 3) make a nutrition claim on the label, or 4) make a claim on the p-o-p material?

Answer: All requirements for nutrient content, criteria for claims, and format must be met except as shown below.

1) Label the package. Values may be declared "as consumed" or "as packaged," number of servings per container need not be included, an optional second column may be used to present information on separable lean of meat and skinless poultry when the products in the package are meat cuts with external cover fat or poultry cuts with skin on, and the simplified format may be used since all food products in the voluntary category meet its use criteria.

2) Use p-o-p material. Values may be declared "as consumed" or "as packaged;" values may be presented on the basis of the RACC since there is no container; values must be declared for meat cuts with external cover fat and skin on poultry and may be declared additionally for separable lean of meat and poultry flesh without skin; the presentation of nutrition information as percent of Daily Values (DV) and listing of Daily Reference Values (DRV) for two calorie levels is voluntary; and, format requirements, e.g., graphic elements and column layouts, are eliminated due to limited space in grocery stores, diversity of current formats for these types of materials, and lack of information on effectiveness of any particular p-o-p format over others.

3) Make a claim on the label. Same as 1 but claims can not be made with reference to an optional second column.

4) Make a claim on the p-o-p material. Same as 2 but the presentation of percent DVs for each nutrient is required and claims can not be made with reference to optional declarations.

24. **Question:** Can a food falling into the voluntary program category be labeled both "as consumed" and "as packaged"?

Answer: No. The final rule specifies that values be declared either "as consumed" or "as packaged."

25. **Question:** When can dual declarations be made?

Answer: Dual declarations can be made to declare both "as packaged" and "as consumed" or "as prepared" values for products under the mandatory program; to declare both values for meat with cover fat and separable lean only or poultry with and without skin for products under the voluntary program; to declare both values for the serving size and 100 grams, 100 milliliters, or one ounce for products under both programs; to declare both values for the serving size and one unit of a product in a multi-serving container where the serving size is more than one unit; and, to list separate declarations for Daily Values on foods purported to be for use both by infants and children under 4 years of age.

26. **Question:** Can values representing more than one cooking procedure be shown in optional columns?

Answer: Yes. The criteria are only limited in that the preparation and cooking instructions are clearly stated.

II. EXEMPTIONS

1. **Question:** If a product is produced and sold in the same state, i.e., not shipped in interstate commerce, is it exempt from these regulations? If a product is shipped directly to a state from Canada or another foreign country and sold only in that state, does it become exempt?

Answer: No to both questions. The only exemptions from the regulations are those listed at 9 CFR § 317.400 and 381.500.

2. **Question:** Would it be useful for labels of products that are exempt to carry a disclaimer such as "not intended for retail sale" or "for further processing"?

Answer: It is up to the manufacturer to determine its own exemption status, and such a statement can not be used to avoid compliance with the regulations.

3. **Question:** Under the small business exemption, are the companies or the products exempted?

Answer: The criteria for both are applied and neither one alone can be used to qualify for an exemption. First, the

business must have 500 or fewer employees, which is the Small Business Administration's definition. Second, the product must be produced in less than the allowed amount, i.e., 250,000 or less pounds from July 1994 to July 1995; 175,000 or less pounds from July 1995 to July 1996; and, 100,000 or less pounds in each year after July 1996. If a business has 500 or fewer employees, it does not have to label product produced at 250,000 or less pounds during the first year but does have to label product produced in amounts over 250,000 pounds. If a business has over 500 employees, it can not be exempt based on production and would have to label product produced at 250,000 or less pounds in the first year.

4. **Question:** Over what period of time should the calculation for the amount of pounds produced be based?

Answer: FSIS intends to amend the regulations to clarify that the most recent 2-year average of business activity should be used.

5. **Question:** Would the time frame run from July to July?

Answer: No. It would be based on a company's usual yearly business activity or fiscal reporting periods, which might differ among businesses.

6. **Question:** How is a business defined?

Answer: A business is a single-plant facility or multi-plant company/firm. The qualification for a multi-plant company entails the total annual production and total number of employees for all facilities under the multi-plant company, not for each individual facility.

7. **Question:** Is a firm exempt when it is a partially owned subsidiary of a multi-plant firm and would otherwise qualify for exemption because it has less than 500 employees?

Answer: If the parent company has a controlling interest in the firm, i.e., the parent concern owns, controls, or has power to control 50 percent or more of its voting stock, the firm is not exempt. Affiliation through stock ownership is described more fully in 13 CFR, Chapter 1, Small Business Administration, at § 121.401(e).

8. **Question:** In determining the 500 employee exemption level, are the number of employees on board during seasonal peaks counted or are the number of employees averaged across seasons? How are part-time employees counted? Over what period of time should the determination be made?

Answer: Following the Small Business Administration's guidelines, the number of employees, which includes employees of domestic and foreign affiliates, would be averaged over the preceding completed 12 calendar months. Part-time and temporary employees are counted as full-time employees over the same period. See 13 CFR at § 121.404 and 121.407.

9. **Question:** Are contractors considered to be employees of a business?

Answer: In certain circumstances employees of an independent contractor may be considered to be employed on another basis. Examples of such circumstances are described in 13 CFR § 121.404.

10. **Question:** Where firms have been in business less than 2 years or products have not been produced for 2 years, how would the exemption be determined?

Answer: FSIS intends to amend the regulations to allow such firms to make reasonable estimates that the number of employees and pounds of products will not exceed the allowed levels on an annual basis.

11. **Question:** If a business qualifies for an exemption but, during the course of future business activity, loses the exemption status, how long will it have to come into compliance with the regulations?

Answer: The business will have one year in which to comply.

12. **Question:** Is a product defined as one that is approved on a single label request for the purpose of the small business exemption?

Answer: No. The product is defined as a formulation, exclusive of flavors which do not significantly alter nutrient content, sold in any size package in commerce.

13. **Question:** What are examples of flavors that might meet these conditions?

Answer: Examples are flavor extracts, food colors, many herbs, many spices and spice blends, and dehydrated condiment-type vegetables when used at low levels. However, not all flavors contain insignificant amounts of required nutrients when used at low levels, e.g., paprika, red pepper, and chili powder.

14. **Question:** During the third year of implementation, if a new product is produced in an amount nearing 100,000 pounds within 6 months, can the formulation be changed, such as by substituting one vegetable for another, and the second formulation qualify for the exemption?

Answer: No. The second formulation would be viewed as a replacement or variation of the first product and would reasonably be expected to be produced annually at a 200,000 pound level based on performance of the initial product.

15. **Question:** A company produces a ham product of a particular formulation and part is sold fully cooked and part is sold uncooked. Are these hams considered to be the same product because the ingredients are identical?

Answer: No. The manufacturing process is part of the formulation and these two products would have significantly different nutrient profiles due to the heat treatment applied. These are two distinct products.

16. **Question:** A company produces a ham product and part is destined to be sold at retail and part sold by the company in gift packs which also contain pancake mix and syrup produced by a different company. For purposes of counting production of the ham product towards a small business exemption, would it be considered as one product and who is responsible for labeling the pancake mix and syrup if the individual foods are labeled as opposed to the entire contents of the gift pack?

Answer: The ham product is a single product and the first company selling the gift pack is responsible for ensuring that the gift pack is properly labeled. Labeling of gift packs is flexible in that package inserts may be used.

17. **Question:** If a company qualifies for the small business exemption based on number of employees and produces a product sold at retail in less than the allowed poundage and to food service in over the allowed poundage, is the product sold at retail exempt?

Answer: No. The food service and small business exemption can not be combined.

18. **Question:** If a company qualifies for the small business exemption based on number of employees and produces a product for food service at over allowed amounts but sells part of the product at discount rates to its own employees, must the product sold to the employees be labeled?

Answer: Yes. Because the product is offered for sale to the employees, that part of the product must be labeled.

19. **Question:** Does the small business exemption apply to foreign firms exporting to the U.S. and on what basis - total production of a product or only production for the export market?

Answer: Exemptions for foreign firms are the same as for U.S. firms and would apply to total production. The exemption size is a measure of the firm's ability to nutrition label its products without undue economic hardship. The exemption for U.S. firms also is based on total production including export market.

20. **Question:** For product imported into the U.S., does the exporter or the importer get the exemption?

Answer: The exporter would get the exemption unless the importer reprocesses or repackages the product under official inspection.

21. **Question:** What type of records need to be kept on number of employees and product production to substantiate a small business exemption, and will FSIS be maintaining copies of any records for this exemption?

Answer: It is up to each company to maintain records adequate to support such an exemption. FSIS will not maintain copies of these records but will review company records on an ongoing basis as directed by Regulatory Programs.

22. **Question:** How will the small business exemption need to be substantiated by foreign manufacturers? Will some sort of certification or substantiation be required of a manufacturer qualifying for exemption when product comes into a port of entry without the required labeling so that the product will not be detained?

Answer: Qualification for a small business exemption is a self certification and the product will not be detained for lack of nutrition labeling. Some foreign countries have expressed interest in certifying the small business status of qualifying firms and FSIS will check exemption status of foreign firms as directed by FSIS headquarters.

23. **Question:** What will be required of deli products, i.e., products sold from the deli case and intended to be sliced?

Answer: These products are exempt unless they bear a nutrition claim or nutrition information because they are portioned at the store to the customers' specifications and rewrapped.

24. **Question:** If the store does not slice the products but sells them whole or in chunks, are they still exempt?

Answer: If manufacturers have reasonable expectations that their products will be sold under conditions where they are portioned and packaged to the customers' specifications, as in a retail store deli, they are exempt. Identical bulk packaged products sold through wholesale clubs and like outlets, where they are not generally portioned and packaged to customer specifications, are not exempt.

25. **Question:** Are items exempt that are tray-packed at a plant versus a supermarket and intended to be sold in the deli department as ready-to-consume?

Answer: No.

26. **Question:** Does the definition of processing as it pertains to retail outlets include repackaging of food sold in bulk packages into retail size packages at the store level?

Answer: Yes. For example, a 25-pound package of hot dogs that will be repackaged at retail would not have to be nutrition labeled unless a nutrition claim was made or nutrition information was provided. However, if the bulk package will be sold directly to consumers, such as through a wholesale club, it would have to be nutrition labeled.

27. **Question:** If a product with a nutrition claim in the brand name is sold in chubs intended for slicing in a supermarket deli where it will be displayed or promoted by brand name, how can the nutrition information be conveyed by the retailer?

Answer: The manufacturer would be required to nutrition label the chubs. Since the retailer would also be making a nutrition claim by virtue of using the brand name, he needs to provide either labels or labeling consistent with the requirements of the regulations to supply the nutrition information to customers. While not required to do so, the manufacturer could provide these as a courtesy to the retailer.

28. **Question:** Does FSIS recognize FDA's "less than 12 square inch" package size exemption policy or only the "40 or less square inch" policy?

Answer: FSIS exempts products weighing less than 1/2 ounce net weight without qualification. FSIS does not exempt products whose labels have 40 or less square inches of available space but allows use of a modified format to present the information. FSIS did not recognize the "less than 12 square inch" policy that allows a label to carry an address or telephone number consumers can use to obtain nutrition information not required to appear on the label. However, FSIS is considering amending its regulations to make this allowance. This option could not be used to meet the requirements of the regulations until it became final.

III. NUTRIENTS

1. **Question:** What is the order of appearance of the optional vitamins and minerals?

Answer: Optional vitamins and minerals are listed after the four underlined mandatory nutrients in the following order: Vitamin A, vitamin C, calcium, iron, vitamin D, vitamin E, thiamin, riboflavin, niacin, vitamin B₆, folate, vitamin B₁₂, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, and copper.

2. **Question:** Must International Units (IU) be used in calculating a Reference Daily Intake (RDI) for vitamin A and how are Retinol Equivalents (RE) converted to IU?

Answer: The RDI for vitamin A for foods for adults and children over 4 years of age is set at 5,000 IU and assumes 2,500 IU as retinol and 2,500 IU as β -carotene. The 5,000 IU allowance value is equivalent to 1,000 RE. When measuring the vitamin A activity of individual foods, the following conversions are used: One IU is equivalent to 0.3 microgram (mcg) of retinol, 0.6 mcg of β -carotene, or 1.2 mcg of other provitamin A carotenoids; one RE is equivalent to 1 mcg of retinol, 6 mcg of β -carotene, or 12 mcg of other provitamin A carotenoids; and, one RE equals 3.33 IU of retinol or 10 IU of β -carotene or other carotenoids.

3. **Question:** What Daily Reference Values (DRVs) and RDIs are established for protein for the purpose of listing protein as a percent of Daily Value (% DV)?

Answer: The DRV for protein for adults and children 4 or more years of age is 50 grams. The RDIs for protein for children less than 4 years of age, infants, pregnant women, and lactating women are established at 16 grams, 14 grams, 60 grams, and 65 grams, respectively.

4. **Question:** Can protein be expressed as % DV on foods for adults and children over 4 and how should it be calculated?

Answer: The % DV for protein must be listed for these foods when a claim is made about protein, and it may also be presented voluntarily. When protein is listed as a percent of the 50 gram DRV and expressed as % DV, the actual amount of protein in grams per serving is first corrected by multiplying the amount by its amino acid score corrected for protein digestibility before dividing by 50 grams and converting to percent.

5. **Question:** Will the values for the RDIs for adults and children over 4 years of age, which are the same as the U.S. RDAs established in 1973, be changed in the near future?

Answer: Under the provisions of the Dietary Supplement Act of 1992, FDA may propose after December 31, 1993 new values for these RDIs, establish RDIs for new nutrients for this group, and establish RDIs for other specific groups for which label reference values are not codified now. FSIS can not speculate further on actions FDA may take in this area.

6. **Question:** Does total carbohydrate include dietary fiber?

Answer: Yes. Total dietary fiber must also be listed separately as a subcomponent under total carbohydrate.

7. **Question:** Does total fat, which is defined as total lipid fatty acids expressed as triglycerides, include cholesterol?

Answer: No.

8. **Question:** When grams of saturated, monounsaturated, and polyunsaturated fat are calculated for listing on the nutrition panel, how is the glycerol component of fat dealt with in determining amounts of specific fatty acids?

Answer: Values are expressed as free fatty acids and the glycerol portion is not included in the gram amount per serving. If the fatty acids are measured as their esters, the ester weight of a fatty acid is converted to the fatty acid weight using conversion factors based on the molecular weights of the individual esters and corresponding free fatty acids.

9. **Question:** Should the sum of saturated, monounsaturated, and polyunsaturated fatty acids equal the total fat content?

Answer: No. The sum of the fatty acids is lower than the weight of total fat by the weight of trans fatty acids,

glycerol, and other non-fatty acid components of structural lipids that are not triglycerides.

IV. FORMATS

1. **Question:** When can the FSIS simplified format be used?

Answer: The simplified format, which FSIS formerly called abbreviated, may be used when one or more required nutrient other than a core nutrient (calories, total fat, sodium, total carbohydrate, or protein) is present in an insignificant amount. The insignificant nutrient(s) may be omitted from the vertical column in the display area, provided a statement "Not a significant source of _____." appears on the nutrition panel with the blank space containing the name(s) of the insignificant nutrient(s).

2. **Question:** What are insignificant amounts of nutrients?

Answer: These are amounts that are permitted to be shown as zero on the nutrition panel, e.g., less than 5 calories, except that for total carbohydrate, protein, and dietary fiber, the amount is less than 1 gram. A technical amendment will be made to indicate that an insignificant amount of sugars is also less than 1 gram.

3. **Question:** If only one core nutrient out of the 14 required nutrients were present in an insignificant amount, could a simplified format be used and how would that core nutrient be listed?

Answer: The simplified format could not be used. The core nutrient would be listed in the vertical column as zero unless it were total carbohydrate or protein in an amount between 0.5 gram up to but not including 1 gram, in which case it could be listed either as 1 gram or with a statement "Contains less than 1 gram" or "less than 1 gram" next to the name of the nutrient.

4. **Question:** If a product qualifies to use the simplified format, but the company wants to list a voluntary nutrient or make a claim about a required or voluntary nutrient, can it still use the simplified format?

Answer: Yes. The manufacturer only needs to add the voluntary nutrient at its appropriate display position.

5. **Question:** Is the entire footnote used with the standard format, which lists DRVs as Daily Values for 2,000 and 2,500

calorie diets and the caloric conversion information, required to be used on the simplified format and the modified format for intermediate sized packages with 40 or less square inches of available space?

Answer: No. The footnote can be shortened to include only the statement "Percent Daily Values are based on a 2,000 calorie diet." If the term Daily Value is not spelled out in the heading but abbreviated as "DV," a statement to the effect that "DV" represents Daily Value is required.

6. **Question:** If a product qualifies to use the simplified format but the manufacturer elects to list the insignificant level nutrient(s) as zero in the vertical column as opposed to showing it by name in the statement at the bottom of the panel, can the footnote still be shortened?

Answer: Yes.

7. **Question:** What is the primary difference between the FSIS simplified format and FDA's simplified format and why didn't FSIS elect to use the FDA simplified format?

Answer: FDA's simplified format differs in that it can only be used with foods for adults and children over 4 years when the foods contain insignificant amounts of 7 or more of 13 required nutrients (calories from fat are excluded). FSIS does not use this criterion because virtually all meat and poultry products, including muscle meats, would fail to meet it and be precluded from using the format. Both simplified formats allow for optional inclusion of the footnote with the DRVs for two or more calorie levels and the caloric conversion information.

8. **Question:** The nutrition panel of a product that qualifies to use FDA's simplified format and neither contains added vitamins or minerals nor declares voluntary nutrients does not have to include non-core required nutrients present in insignificant amounts in the display area or by name in the statement "Not a significant source of _____." at the bottom of the panel. Does FSIS have the same provision?

Answer: No. When using the FSIS simplified format, non-core required nutrients must be listed either in the display area or by name in the statement.

9. **Question:** Can nutrients be listed as zero at the bottom of the panel instead of using the wording "not a significant source of" in order to save space?

Answer: No.

10. **Question:** What is the difference between FDA's shortened format and the FSIS simplified format?

Answer: FDA's shortened format allows for listing of any non-core nutrient present in insignificant amounts to be shown at the bottom of the panel in the statement "Not a significant source of ____." regardless of the number of nutrients present in insignificant levels and the footnote with the DRVs and caloric conversions may not be dropped. FSIS allows the same listing in its simplified format but the footnote may be dropped.

11. **Question:** Is a break in the vertical alignment allowed with the standard format?

Answer: Yes. One break is always allowed wherein the footnote may be placed to right side of the panel; however, there can be no intervening information.

12. **Question:** When can tabular and linear (string) displays be used?

Answer: Use of both of these displays is restricted to products with 40 or less square inches of labeling space. The tabular display may be used only when the package shape and size can not accommodate a column display on any label panel. The linear display may be used only if the tabular display does not fit on the label.

13. **Question:** Can a tabular display be used when the label has space for the long format but it will wrap around the product and might be inconvenient to read?

Answer: On a case-by-case basis, FSIS will consider allowing the tabular display for packages larger than 40 square inches that have a surface area which precludes the presentation of the full nutrition label.

14. **Question:** When will an example of a linear display be available?

Answer: Examples of linear displays are under review by FDA and FSIS at this time, but this review does not preclude use of a linear display. A sample string for a nutrient with a subcomponent might read as follows: 13 g Total Fat is 20% DV* (5 g of Sat Fat is 25% DV) with the footnote following the completed string for all nutrients. Since this is a modified format, the full footnote is not required.

15. **Question:** Are abbreviations for other than Daily Value allowed?

Answer: Yes. Seven abbreviations are allowed on tabular and linear displays as follows: Serving size - Serv. size; Servings per container - Servings; Calories from fat - Fat cal; Saturated fat - Sat fat; Cholesterol - Cholest; Total carbohydrate - Total carb; Dietary fiber - Fiber. The abbreviations for the nutrients, which are those whose names exceed 10 characters, may be used in the footnote with Daily Values for 2,000 and 2,500 calorie diets.

16. **Question:** Can the product name be placed within the nutrition panel?

Answer: No. The name can be placed just above the box.

17. **Question:** When using a dual declaration, such as for a condensed soup and its prepared form, can the actual quantitative amounts be listed for the prepared form?

Answer: Yes. The additional quantitative amounts can be given immediately adjacent to the required quantitative information for the product described in the first column or the amounts can be given in a footnote.

18. **Question:** When less than 0.5 gram of dietary fiber or saturated fat is present in a serving of a product, the amounts would be shown as zero on the label. However, when the % DV is calculated based on an actual unrounded fiber or saturated fat content of 0.2 grams per serving, the calculation yields 1 percent. Will consumers be confused to see a gram weight of zero in conjunction with 1% DV for the same nutrient and should the % DV be expressed as zero in these cases?

Answer: The regulations do not contain a proviso that % DV should be expressed as zero when rounding of quantitative information results in a value of zero. FSIS is considering amending the regulations to avoid this situation.

19. **Question:** When % DVs for protein and potassium are included on the nutrition panel on foods for adults and children over 4 years, where is the DRV information placed?

Answer: Protein should be listed in the footnote under dietary fiber with the DRV inserted on the same line in the numeric columns. The DRV for protein is based on 10 percent of calories as protein, which equates to 50 grams for a 2,000 calorie diet and 65 grams (62.5 rounded up to 65) for a 2,500 calorie diet. Similarly, potassium would be listed

in the footnote under sodium. The DRV for potassium is 3,500 milligrams for both the 2,000 and 2,500 calorie diets.

20. **Question:** The % DV column and the footnote with DRV and calorie conversion information may not be included on foods for children less than 4 years of age, except that listing of the % DV for protein is required if the protein quality meets certain minimal requirements. The regulations do not contain a provision for placement of the % DV for protein. Should it appear in the upper or lower panel?

Answer: The regulations will be amended to accommodate the % DV listing for protein.

21. **Question:** Where should the nutrition information be placed on the label?

Answer: The nutrition information can appear on the principle display panel or on the information panel, which is the first usable surface, i.e., excluding those with folded flaps, tear strips, etc., to the right of the principal display panel. On intermediate sized packages with 40 or less square inches of available space, the information may appear on any label panel.

22. **Question:** What is contained on the information panel and what are the location requirements, e.g., right side, left side, or in conjunction with the ingredient statement or signature line, for the nutrition information?

Answer: The information panel may contain mandatory information including nutrition information, the ingredients statement, and the firm's name and address and, on cylindrical cans, the inspection legend and number. Policy Memo 007, Information Panel, specifies that, when a surface is larger than needed to accommodate the mandatory information, it should be located in one place without intervening non-mandatory information, e.g., UPC codes, recipes, etc., and on the left side of the surface. It may be positioned near the top, middle, or bottom, but all mandatory information must appear together. This Policy Memo will be rescinded on July 6, 1994 because FSIS received numerous requests to remove these requirements to allow flexibility in placement of the information. FSIS believes that the mandatory information need only be placed to read in the same direction and be generally in the same proximity anywhere on the usable surface area.

23. **Question:** Can nutrition labeling be included on a multi-layer label or as a foldout or pamphlet attached to the primary label for products under the mandatory program?
- Answer:** Yes. However, the mandatory information must be visible to the consumer.
24. **Question:** What is the status of a product that has always used a label that is too small to accommodate a nutrition label, i.e., a 2" X 2" tag attached to a stick of dry sausage which may weigh anywhere from 0.75 to 10 pounds?
- Answer:** Use of tag labels that can not accommodate the mandatory information would not be considered acceptable for containers that have available surface space to carry the required information.
25. **Question:** What does FSIS consider to be the surface area available to bear labeling?
- Answer:** The surface area available to bear labeling includes all the surface area of the container even if it is not traditionally used, e.g., jar lids, bottle necks, or if it is an odd shaped part of a package because there are different opinions about what is practically available or usable space.
26. **Question:** Would the total wrap around a package of frankfurters be considered available space for labeling?
- Answer:** Yes.
27. **Question:** Does FSIS have provisions other than modified displays and small package exemption to allow for use of labeling on foods when lack of space makes it impracticable to provide the information on a label, e.g., on a very small label of a product weighing less than 1/2 ounce which has a nutrient content claim in the brand name?
- Answer:** No. At this time, the regulations do not contain a provision for other alternative means such as a telephone number or address for consumers to use to obtain the nutrition information for the product. Until such a provision is made final, the information would have to be provided by other means, such as a tag affixed to the product, the appropriateness of which would be evaluated at label approval.
28. **Question:** A company produces a variety pack consisting of several single-serve varieties packed together in four or six packs. These are placed on corrugated trays and then a

clear shrink wrap is applied to the entire package. Although the wrap is clear, there is no way to ensure the containers would be orientated so the nutritional panel would be visible. If the product must be nutrition labeled, what information would be required on the label and would the information be allowed to be placed on the bottom of the tray prior to assembly so that the shrink wrap could protect the integrity of the print?

Answer: If the information is obscured on the individual units, the entire package should be nutrition labeled. The information panels for the units could be reproduced on a label and placed on the bottom of the tray as described in the question as long as it is visible to the consumer at the point of purchase.

29. **Question:** If the nutrition label were to cover most of the surface of a meat or poultry product, such as a marinated cut, where consumers might want to see the actual meat surface, would this be sufficient reason to use a modified label or alternate placement?

Answer: Perhaps. Such allowance could be considered on a case-by-case basis at time of label approval.

30. **Question:** Is use of Franklin Gothic Heavy or Helvetica Black and Regular type style required?

Answer: No. A single easy-to-read type style is required of which these are examples.

31. **Question:** Is it necessary to use a nutrition display with a box shape on a round package?

Answer: Yes. The nutrition information must be set off in a box.

32. **Question:** Can selective highlighting, e.g., colored bars, or reverse printing, be used?

Answer: No. Allowing optional highlighting schemes will lead to less consistency among labels. The regulations require that the headings, i.e., Nutrition Facts, Amount per Serving, and % Daily Value* and the names of all required nutrients in the upper panel that are not indented, i.e., Calories, Total Fat, Cholesterol, Sodium, Total Carbohydrate, and Protein, and their percentage amounts (% DV) be highlighted by bold or extra bold type or other highlighting (but not reverse printing as a form of

highlighting) that distinguishes them from other information.

33. **Question:** Does "neutral" background refer to the background color of the package and could you use a red background with black type?

Answer: The nutrition information in the box should generally be in dark or one color type on a white or neutral background, when practical. However, flexibility in type color and background is allowed. Reverse printing can also be used although it might be less legible. It would not be acceptable to use light letters on a light background or dark letters on a dark background to the point that readability suffers. If contrast is adequate and the type legible, black type on a red background could be used.

34. **Question:** Can the print be condensed?

Answer: Yes; however, the letters should not touch.

United States Department of Agriculture

Food Safety and Inspection Service

Room 0157-South Building

Washington, D.C.

20250

OFFICIAL BUSINESS

Penalty for Private Use, \$300

**FIRST-CLASS MAIL
POSTAGE & FEES PAID**

USDA-FSIS

Permit No. G-42

FSIS DIRECTIVE

7310.4
Rev. 2

12-28-93

FOREIGN PARTICLE CONTAMINATION OF MEAT OR POULTRY PRODUCTS

I. PURPOSE

The purpose of this directive is to:

A. Provide instructions for inspection personnel to follow when an official establishment uses devices approved by FSIS to detect foreign particles (such as metal, plastic, rubber, glass) in meat and poultry products in which an incident is known to have occurred and a portion(s) of the product is suspected of being contaminated.

B. Establish provisions for use of a PQC program for foreign particle detection.

II. CANCELLATION

FSIS Directive 7310.4, Revision 1, dated 1/26/88

III. REASON FOR REISSUANCE

To provide establishments with guidelines on obtaining approval from the regional office of a PQC program for detection and elimination of foreign material, in lieu of having to request and obtain approval from the regional office, on a case-by-case basis, of the salvage procedures as provided in PQC Guideline #260. Also, changes have been made throughout the directive to clarify the Agency's policy regarding foreign particle contamination.

IV. REFERENCES

MPI Regulations, Sections 308.5, 310.18, 318.2(d), 318.4, 381.53, 381.78(a), 381.91 and 381.145
FDA Regulations, 21 CFR 179.21
OSHA Standards, 29 CFR 1910.96
FSIS PQC Guideline #260
FSIS PQC Guideline #270
FSIS Directive 8820.1, dated 3/1/91
FSIS Directive 8830.1, dated 3/1/91

V. ABBREVIATIONS

The following will appear in abbreviated form in this directive:

FDA	Food and Drug Administration
OSHA	Occupational Safety and Health Administration
PQC	Partial Quality Control
MPI	Meat and Poultry Inspection
IIC	Inspector in Charge

VI. POLICY

A. FSIS is responsible for assuring that meat and poultry products produced under the Federal Meat Inspection Act and the Poultry Products Inspection Act are wholesome, not adulterated, and properly marked, labeled, and packaged.

B. Managers of official establishments are responsible for preventing product from becoming contaminated and/or adulterated. Occasionally, meat or poultry products accidentally become contaminated. When accidental contamination occurs, the establishment should hold all the product that is suspected of being contaminated. Establishment management may (1) divert the product to non-human food channels, (2) conduct a salvage procedure, using detection equipment and following the PQC program approved by the regional office that follows PQC Guideline #270, or (3) on a case-by-case basis, submit and obtain approval from the regional office of a written product salvaging procedure that follows PQC Guideline #260.

C. In the case of foreign establishments producing product destined for export to the United States, when an incidental contamination is known to have occurred, the procedures specified in Paragraph VIII shall be used to clear product of any particle contamination. Approval of the procedure must be obtained from the foreign country meat inspection authority prior to the operation. Optionally, a PQC program based on Guideline # 270 may be submitted to International Programs for approval.

D. The IIC may permit use of FSIS approved equipment in conjunction with an approved PQC program or a procedure approved

for a specific incident to detect foreign particles such as metal, plastic, rubber, or glass. The equipment used must be capable of detecting particles as small as 1/32" (0.8 mm) for sorting and salvaging product. Any product in which foreign particles are visually or organoleptically detected after passing through the detection equipment must be handled according to MPI Regulations, Sections 301.2(c), 310.18, 314, 318.2(d), 381.1(b)(4), 381.36, 381.91(b), 381.95 and 381.145.

E. Product contaminated with other substances, such as toxic chemicals, cannot be salvaged using mechanical detection equipment and must be handled according to the MPI Regulations cited in the previous paragraph.

F. The use of a PQC salvage program is only allowed for occasional accidental contamination incidents. Frequent or routine contamination incidents indicate inadequate process control which will cause the inspector to apply the corrective and progressive enforcement action procedures as provided in FSIS Directives 8820.1 and 8830.1. If routine contamination incidents continue, PQC programs will be suspended by the inspector and the procedures for a case-by-case approval will be followed.

G. **EXCEPTIONS:** Exceptions to this directive are as follows:

1. Routine in-line screening devices voluntarily installed by establishment officials and product in which these screening devices detect one or several bits of particulate matter.
2. Product in which the inclusion of a missing component, such as a bolt or blade, can be shown to be still intact. In this case, any reasonable establishment procedure, concurred by the IIC, may be used to isolate and show that no portion of the component is missing.
3. Product that is known to be contaminated and unsalvageable. In this case, the contaminated product is subject to condemnation.
4. Product such as whole birds, parts, meat cuts or individual pieces on which there is only non-toxic surface contamination that can be seen visually. In this case any reasonable establishment procedure, concurred with by the IIC, may be used to recondition product before it is presented for visual reinspection.

VII. ACCEPTABLE DETECTION EQUIPMENT

A. All detection equipment must be acceptable to the Facilities, Equipment and Sanitation Division, Equipment Branch,

as set forth in MPI Regulations, Sections 308.5 and 381.53.

B. Equipment used to re-examine product placed "on hold" by the establishment for suspicion of particulate contamination must be capable of detecting particles of 1/32" [.031 inch (0.8mm)] in the greatest dimension. Spheres of 1/32" [.031 inch (0.8mm)] diameter are acceptable for use in determining detection capability.

C. Prior to the detection operation, such equipment must be tested with seeded samples. The testing must be done at the same rate of speed that will be used to process the suspect product.

D. The samples must be of the same size, shape, and consistency as the product placed on hold by the establishment. The samples should be seeded with appropriately sized contaminants of the same type material which the detection equipment is intended to detect, and sufficiently identified to make retrieval easy. Precautions need to be taken to prevent the seeded samples from being included in product intended for human consumption.

E. At the discretion of the IIC, the seeded sample testing process shall be used 2-4 times per hour during the actual re-examination of the suspect product to assure that the detection equipment is operating properly.

F. X-Ray Detection Equipment

1. X-ray detection equipment must comply with special safety requirements as follows:

a. The equipment must comply with the FDA Regulations, 21 CFR 179.21. The applicable part of this regulation states that the radiation source must be X-ray tubes producing X-radiation from operation of the tube source at energy levels of 300 kilovolt peak or lower.

b. The equipment shall bear a label identifying the source of radiation and maximum energy of radiation emitted by X-ray tube sources. This label or accompanying labeling material must also bear: (1) adequate directions for installation and use, and (2) a statement that no food shall be exposed to the radiation sources listed above so as to receive an absorbed dose in excess of 1,000 rads.

c. The X-ray equipment and the room or area where it is installed must have a sign that reads "Caution-Equipment Produces X-rays When Energized," or a similar sign that conveys the same message.

d. The X-ray equipment:

(1). Shall be equipped with a power indicator light.

(2). Should be key controlled, with access to keys restricted to authorized users.

(3). Will be operated by experienced and trained individuals and will follow the instructions provided by the manufacturer.

2. Whenever X-ray equipment is used, the establishment should maintain records which address:

a. The food treated.

b. Lot identification.

c. The scheduled process showing evidence of compliance with such process.

d. The ionizing energy source and source calibration.

e. The date of X-ray processing.

f. The type of equipment used (make and model).

g. Location of the X-ray equipment.

h. The name(s) of persons authorized to operate the equipment.

3. Federal and State laws require establishment employees and inspectors to wear radiation monitoring badges when working in the X-ray inspection area. If an establishment has a PQC program or procedure for foreign material detection, assigned badge service should be initiated for each inspector. The IIC should contact the Program Management Office in the regional office to obtain the dosimeter badge(s). Dosimetry badges for inspection personnel are available from the Agricultural Research Service through the FSIS regional offices. Inspectors are required to wear the badges when working in the vicinity of X-ray detection equipment.

4. If a TV-type screen is used to monitor products

for contamination, operators monitoring the screen must be relieved periodically to avoid eye/body fatigue and reduce the chance of missing visual detail.

VIII. PROCEDURAL GUIDE FOR EXAMINING CONTAMINATED PRODUCT

When a product is suspected of being contaminated, it must be either condemned or re-examined to detect and remove any particle 1/32" [.031 inch (0.8mm)] or larger, in the largest dimension. Product re-examination will follow the approved PQC program, developed according to PQC Guideline #270, or will follow an approved written salvage procedure as prescribed in PQC Guideline #260 which was developed for a specific contamination incident. In either case, the following will apply:

A. At the IIC's discretion, seeded samples may be passed through the screening operation without the knowledge of the operator who monitors the process, thereby verifying the ability of both the equipment and the operator to detect the contamination.

B. If the operator/equipment monitoring the process is unable to identify the seeded sample, all product re-examined after the last identified seeded sample must be rerun or disposed of as non-human food.

C. If the operator/equipment fails repeatedly, re-examination of contaminated product will cease until a more satisfactory method can be devised and approved, or the product is diverted from human food use.

IX. RESPONSIBILITIES

A. The IIC will:

1. Retain all suspect contaminated product and await a decision from the establishment as to what course of action the establishment wants to pursue.

2. Notify the regional office, through supervisory channels, each time suspect product is re-examined.

3. Supervise the destruction of the entire lot or code if the establishment chooses to destroy it, or supervise the destruction of product which is still contaminated after the re-examination is completed.

4. If the establishment elects to re-examine the suspect contaminated product in accordance with an approved foreign material detection PQC program, verify that the establishment is following the approved PQC program.

5. If the establishment does not have an approved foreign material detection PQC program and elects to re-examine the suspect product, secure a written procedure from the establishment. Such procedure must comply with Paragraphs VIII. and IX. of this directive and, in addition, include the following information:

- a. Description of the product (including amount).
- b. Identity and description of the contaminant.
- c. Explanation of how the contamination occurred.
- d. Date that the contamination occurred.
- e. Lots or codes involved.
- f. Present status and location of product.
- g. Detailed description of intended detection operation, including sorting, reconditioning and/or disposition of the product.
- h. Steps that will be taken to reduce the risk of future incidents of similar contamination of product.

6. Review the proposed program or the procedure and forward it, along with any comments, to the Regional Director through supervisory channels. The program or the procedure should not be submitted if the establishment elects to destroy the entire lot or code of the contaminated product.

7. After the program or the procedure is approved by the Regional Director, monitor all aspects of the detection process, including the adequacy and competency of establishment personnel conducting the operation.

B. The Area Supervisor will:

1. Review the establishment's proposed PQC program or one-time product salvage procedure.

2. Assure that the explanation of how the product became contaminated is accurate.

3. Assure that the establishment has taken steps to

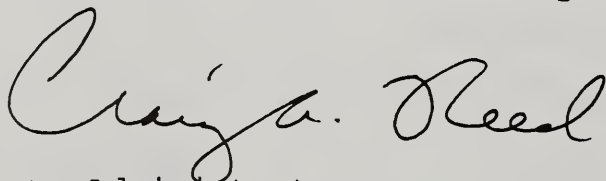
prevent similar future contamination of product.

4. Forward the program or the procedure, along with any comments, to the Regional Director.

C. The Regional Director will:

1. Review the recommendation submitted by the IIC and Area Supervisor and make the final decision regarding the acceptability of the proposed PQC program or of the one-time product salvaging procedure.

2. Coordinate with Processed Products Inspection Division, Science and Technology, or Processing Operations Staff, Inspection Management Program, Inspection Operations, if unusual circumstances are involved or guidance is desired.



Deputy Administrator
Inspection Operations

United States Department of Agriculture

Food Safety and Inspection Service

Room 0157-South Building
Washington, D.C.
20250

OFFICIAL BUSINESS

Penalty for Private Use, \$300

FIRST-CLASS MAIL

POSTAGE & FEES PAID

USDA-FSIS

Permit No. G-42

37/414MPSLD1594 R1 103-0001
E2
US DEPT OF AGRICULTURE
FOOD & NUTRI INFORMATION CNTR
NAT'L AGRI LIBRARY, RM 304
BELTSVILLE MD 20705-2351

FSIS DIRECTIVE

7370.1

9/28/93

INSTRUCTIONS FOR VERIFYING INTERNAL TEMPERATURE AND HOLDING TIME OF MEAT PATTIES

I. PURPOSE

This directive clarifies the method to be used by FSIS personnel to determine the minimum internal temperature and holding time of cooked meat patties. On September 1, 1993, the regulation "Heat-Processing Procedures, Cooking Instructions, and Cooling, Handling and Storage Requirements for Uncured, Meat Patties" became effective. Applicable products include items such as cooked hamburger, salisbury steaks, breaded and battered chopped veal steaks, and pork sausage patties. In addition, this directive will assist inspection personnel when performing the appropriate interim Inspection System Guide temperature/time tasks specified in FSIS Notice 53-93, Performance-Based Inspection System (PBIS) Tasks for Heat-Processed, Uncured Meat Patties. As described in this directive, only thermocouple thermometers should be used to verify cooked patty temperatures.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

MPI Regulation, Section 318.23
FSIS Notice 53-93, dated 9/28/93
FSIS Directive 8820.1, Rev. 1, dated 3/1/91

V. BACKGROUND

A. Patties, by the very nature of their shape, present a challenge in determining the internal temperature, especially of the "just-cooked" patty. Most patties are cooked as they travel on a conveyor belt through a broiler or fryer. Heat is transferred from the cooking medium (i.e., gas flames, hot oil) to the meat patty. The surfaces of the patty become the hottest and the heat transfers from the exterior of the patty to the

interior by conduction. That is, the surface particles of meat get hot and transfer some of that heat to the neighboring cooler particles and so on, until eventually, the entire patty would be of the same temperature. This process is cut short by removing the patty from the heat source. However, the outer, extra hot particles of meat continue to transfer some of their heat to the cooler interior portions of the patty and may continue to increase the internal temperature of the patty by 3°F or more over what it was when first removed from the heat source.

B. The typical dial thermometers used by many of the FSIS field personnel are designed to operate with the entire lower portion of the probe inserted into the meat product. The 2-inch "sensing" portion of the probe gives a reading that is an average of the temperatures along its length. This is not much of a significant problem when verifying the temperature of a sauce or a roast. However, the temperature gradient in a patty can be from >200°F. on the surface to <140°F. in the interior. Averaging the temperature gradient results in a faulty reading for the "internal temperature" of the patty and may indicate a fully-cooked patty when, in fact, one does not exist. There are newer, more accurate temperature sensing devices available.

C. Thermocouple thermometers will be used to verify the temperature of cooked meat patties. The thermocouple thermometer is used in the same manner as the traditional thermometer; however, the sensitive portion is restricted to the very tip of the probe. The probe itself is a smaller diameter (1/16") allowing easier insertion into the center of a thin patty. The dial is replaced by a hand-held digital read-out device. These thermometers are also more fragile and much more expensive than the dial thermometers. The inspectors receiving a thermocouple thermometer will also receive instructions for care and maintenance. The instrument and probe must be kept clean. Regular wiping with a damp cloth will usually suffice. If extra cleaning is necessary, only mild soaps should be used; never any form of solvent.

VI. RESPONSIBILITIES

A. Establishment Responsibilities: Controlling the process through process monitoring and assuring that the finished product is in compliance with the requirements of MPI Regulation, Section 318.23.

B. Inspector Responsibilities:

1. Monitoring the compliance of cooked meat patties with the regulatory requirements for heat-processing procedures, cooking instructions, and cooling, handling, and storage requirements, as directed through PBIS.

2. Taking appropriate action when results indicate non-compliance with the regulations, as specified in FSIS Directive 8820.1, Rev. 1.

VII. INSTRUCTIONS

When verifying cooked meat patty temperatures, the inspector should:

A. Verify the Accuracy of the Thermocouple Thermometer.

1. All thermometers require calibration to be accurate. Thermocouple thermometers contain electronic components that are not accessible to the user. These thermometers are calibrated at the factory against an instrument traceable to the National Institute of Standards and Technology. If properly used, the thermocouple thermometer should stay correctly calibrated for 2 to 3 years.

2. Calibration of the thermometer should be checked at 32°F., the freezing temperature of water. A freely draining, melting ice bath may be used for medium at 32°F. It is important that the probe of the thermometer not be allowed to rest on the bottom of the container of freezing water. Allow the thermometer to remain in the water bath for 1 minute before taking the reading. It is best to compare the reading of the "test" thermometer with the reading of a mercury-in-glass thermometer that is of known accuracy.

3. Calibration of the thermometer should be checked at 212°F., the boiling temperature of water. Boiling water is used for medium at 212°F. Water boils at a simmer; it need not be a rolling boil. It is important that the probe of the thermometer not be allowed to rest on the bottom of the container of boiling water. Allow the thermometer to remain in the water bath for a minute before taking the reading. It is best to compare the reading of the "test" thermometer with the reading of a mercury-in-glass thermometer that is of known accuracy.

4. If the reading on the thermocouple thermometer is off by more than 1°F., then it should not be used. Contact your immediate supervisor for a replacement and return the inaccurate unit for servicing. Contact the regional office for shipping instructions.

B. Verify Patty Temperature.

1. **Sanitizing the probe and patty disposition.** The probe must always be cleaned and sanitized prior to performing a temperature verification task. After a temperature is taken of product which does not comply with the time/temperature regulation, as in Paragraph VIII, B., 3., reclean and sanitize the probe. All patties used by inspection personnel to determine compliance with the time/temperature regulation should be returned to plant management for disposition.

2. **Tempering.** A thermometer at room temperature cannot be inserted directly into a hot patty without having some cooling effect on it. The relative coolness of the probe acts to chill the patty, while the heat of the patty warms up the probe. Insert the probe into several patties successively to warm it up to the desired range before taking a verification temperature.

3. **Checking for "cold spots".** If patties exit a cooker in several rows across a conveyor belt, it is necessary to take the temperature of a patty from each row, one at a time, to determine the existence of "cold spots". For taking verification temperatures, select a patty from the coldest row.

4. **Inserting the probe.** As quickly as possible, remove the patty from the conveyor, and insert the thermocouple probe. Insert the probe from the side of the patty, putting the sensitive area as close to the geometric center of the patty as possible.

NOTE: It is important not to stack the patties and insert the thermometer through the center of the stack. With the much smaller thermocouple probe, inserting the probe into a very thin patty will not be as difficult as it is with the dial thermometers. Only thermocouple thermometers should be used to verify patty temperatures.

5. **Reading the temperature.** Allow time for equilibration after the thermometer is inserted into the patty. This should take only a couple of seconds. Do not "help" the thermometer along by tapping the patty or wiggling the probe. Gripping the patty between the fingers should also be avoided. Take note of the highest temperature registered by the thermocouple thermometer. This is the "**minimum internal temperature**" of the patty.

6. **Rounding rules.** The thermocouple thermometers are calibrated to read in 0.1°F. increments. These readings may be rounded off to the nearest whole number. Thus, a digital read-out of 150.5 to 150.9°F. shall be viewed equivalent to 151°F.

C. Verify Holding Time. The heat processing requirement of the patty regulation addresses not only internal temperature, but also holding time. After the patty reaches the **"minimum internal temperature,"** the time must be monitored to assure that the product maintains at least that temperature for the required time. Any timepiece which reads seconds may suffice. This includes stopwatches, wristwatches, and pocket watches. Timing devices that are preset and tripped to begin countdown are acceptable so long as they are incremented in seconds. An establishment may make available to the inspector a timing device identical to the one used by establishment personnel.

VIII. TEMPERATURE/TIME COMBINATIONS

A. The patty regulation allows manufacturers the option of several time/temperature combinations. The establishment should make available which time and temperature combination will be used on each lot prior to the production run.

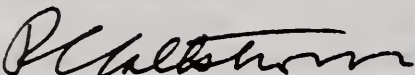
B. Heating Deviations and Corrective Actions:

1. Example of a heat process in compliance: Assume the manufacturer chooses the time/temperature combination of 16 seconds at 155°F. The thermometer shows a temperature reading of 155°F when first inserted, then travels to 156°F and 157°F. before coming back to 155°F. The time interval between the first registered reading of 155°F. and then subsequently rising and then falling below 155°F. is eighteen seconds. The heat processing is in compliance.

2. Example of a heat process which may require additional monitoring: A deficiency would not be documented if the establishment fails to meet their selected temperature/time combination but does meet another temperature/time combination as shown in Table A of the MPI Regulations, Section 318.23. Although not considered a deficiency, this situation may indicate a lack of process control. Therefore, the inspector may decide to perform additional unscheduled tasks to ensure that one of the temperature/time combinations as provided in Table A is met.

3. Example of a heat process not in compliance: It may be that the product does not comply with any of the temperature/time combinations listed in the regulation. The product is not in compliance and must be handled as specified in §318.23(c)(2), Requirements for Handling Heating or Cooling Deviations of the MPI Regulations. The product may be reprocessed or used as rework in product that is to be heat processed to one of the temperature/time combinations, or relabeled as partially-cooked product.

Any questions regarding this directive should be referred to the next level of supervision.

for 
Deputy Administrator
Inspection Operations

FSIS DIRECTIVE

7410.2
Rev. 1

10/6/93

PACKAGING MATERIALS MONITORING

I. PURPOSE

This directive provides guidelines for complying with the packaging monitoring requirements contained in Sections 317.24(d) and 381.144(d) of the MPI Regulations. ■

II. CANCELLATION

FSIS Directive 7410.2, dated 9/20/85 ■

III. REASON FOR REISSUANCE

This revision updates references to MPI Regulations, Sections 317.24 (formerly designated as 317.20) and 381.144(d); FSIS Directive 11,000.2 (formerly Part 8.34 of the MPI Manual). ■
It revises FSIS Form 11,300-11 (formerly FSIS Form 6800-11). ■
This revision also updates the phone number, mailing address, and organization structure for the Product Assessment Division, ■
Compounds and Packaging Branch (formerly Food Ingredient ■
Assessment Division, Product Safety Branch), Regulatory ■
Programs. ■

IV. REFERENCES

21 CFR 7.12 and 7.13, FDA Regulations;
MPI Regulations, Sections 301.2, 317.24, 381.1, and 381.144;
FSIS Directive 11,000.2 dated 4/28/87;
FSIS Directive 7410.1, Rev. 1, dated 7/1/93; ■

V. ABBREVIATIONS AND FORM

The following will appear in their abbreviated form in this directive:

FFDCA	Federal Food, Drug, and Cosmetic Act	
IIC	Inspector In Charge	
PAD	Product Assessment Division	■
CPB	Compounds and Packaging Branch	■
IO	Inspection Operations	■

FSIS Form 11,300-11--Packaging Material Monitoring ■

VI. POLICY

MPI Regulations, Sections 317.24 and 381.144, note that official establishments must receive from the suppliers of their packaging materials and retain in their files, written guaranties that the materials comply with the FFDCA, as amended, and all applicable food additive regulations. Such guaranties establish that the described packaging materials are in compliance unless the inspector has specific reasons to believe otherwise. FSIS will monitor the use of packaging materials in official establishments to ensure that the written guaranties can be substantiated. ■

VII. INSPECTOR'S RESPONSIBILITIES

A. The IIC shall:

1. Receive FSIS Form 11,300-11, (See Attachment 1), which will be forwarded to randomly selected establishments by the CPB. ■

2. Select a specified number of packaging material(s) (one material per monitoring form) during the timeframe indicated on the monitoring form. If possible, different kinds of materials (e.g., cans, plastic film, etc.) should be selected and the material(s) should be currently in use at the establishment and covered by a guaranty.

3. Provide the necessary information as indicated on the monitoring form. Most of this information can be taken directly from the guaranty. If no material is used at the establishment, *** the IIC should write "NONE" in Item 1 *** and complete Item 6. ■

4. Use the self-addressed envelope that accompanies the monitoring form and return it completed to CPB. **A sample of the packaging material should not be submitted.**

5. Allow continued use of a material during the review period. Selection of a material for review does not affect a material's acceptability. If the acceptability of a packaging material cannot be confirmed, the IIC at the establishment where the material was selected for review will be notified by Headquarters IO office. Subsequently, an FSIS listing of selected materials will be issued to inform all other establishments.

VIII. REVIEW REQUIREMENTS

A. CPB will review the information provided by the IIC on FSIS Form 11,300-11. If CPB does not have the complete chemical composition of a packaging material that has been selected, a letter (See Attachment 2) will be sent to establishment management with copies to the IIC and the packaging material supplier. CPB will assign a Monitoring Control Number to each monitoring form. This number must be included on all correspondence from establishment management or the material supplier in order to track the progress of the *** evaluation of the selected packaging material.

B. CPB will review additional information requested in Attachment 2 that would verify the basis for the supplier's guaranty.

1. The establishment/supplier will have a minimum of 30 days to submit the information. The information should include, but not necessarily be limited to: manufacturing firm's name, brand name or code designation for the material, complete chemical composition, and intended use of the selected material. The Monitoring Control Number, as shown at the bottom of Attachment 2, should be included on all correspondence from the establishment or packaging supplier concerning that packaging material.

2. If CPB does not receive a reply from the packaging material supplier within the timeframe specified, a

final notice (See Attachment 3) will be sent to establishment management with copies to the IIC and the packaging material supplier. ■

3. If no response to the final notice is received and the safety and/or acceptability of the material cannot be confirmed, continued use of the packaging material may be denied in accordance with the procedures in MPI Regulations, Sections 317.24(e) and 381.144(d). If use of a packaging material is denied, the IIC at the establishment where the material was selected for review will be notified by Headquarters IO office. Subsequently, an FSIS listing will be issued to inform all other establishments. ■ ■ ■

C. Inspectors shall not take action to prevent use of the material until official notification is issued.

IX. NOTIFICATION OF UNACCEPTABLE MATERIALS

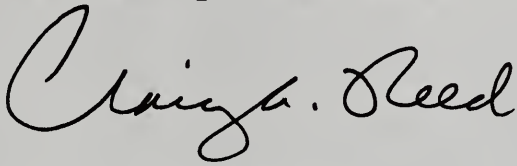
If the use of a material is denied by the Administrator, the IIC at the establishment where the material was selected for review will be immediately notified by the Headquarters IO office. Also, FSIS will periodically issue to inspectors a listing, by distinguishing brand name or code designation and by the supplier's name and address, of packaging materials that have been reviewed and have failed to meet the requirements of the FFDCA, as amended. Materials listed are those not permitted for use in official establishments. If a subsequent review of any material indicates that it meets the requirements of the FFDCA, a letter will be issued to the packaging material supplier superseding the listing. This letter will serve as proof of acceptability until a subsequent listing is issued. ■

A. Upon receipt of notification by the Headquarters IO office or the FSIS listing, the IIC will take the following actions: ■

1. Follow instructions given in the notification of unacceptable materials, which will be sent by the Headquarters IO Office. ■

2. Review the FSIS listing to determine if any listed materials are in use at the establishment. The inspector **should not** allow materials listed in the FSIS listing to be used in official establishments unless notified otherwise. Unless an imminent hazard to public health exists, no product recalls or repackaging should be required. The disposition of materials

already in the establishment, which appear in the FSIS listing, and of food products packaged in such materials, will be handled on a case-by-case basis in the notification.

A handwritten signature in black ink, appearing to read "Craig Reed". The signature is fluid and cursive, with the first name "Craig" and last name "Reed" clearly distinguishable.

Deputy Administrator
Inspection Operations

Attachments

- 1 -- FSIS Form 11,300-11
- 2 -- Example--FSIS Letter to Establishment
- 3 -- Example--Final FSIS Letter to Establishment

FSIS Directive 7410.2
Revision 1
Attachment 1

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, D.C. 20250	MONITORING CONTROL NO. _____
	COLLECT DURING WEEK OF: _____

PACKAGING MATERIAL MONITORING

Return to: USDA, FSIS, RP, PAD
Compounds and Packaging Branch
Building 306, Room 300, BARC-East
Beltsville, MD 20705

FSIS monitors the use of food contact packaging materials (Refer to FSIS Directive 7410.2) in official establishments to assure that they conform to the requirements of the Federal Food, Drug, and Cosmetic Act. This plant was randomly selected.

- * Provide the information indicated below on a food contact packaging material.
- * The packaging material must be in use at this plant.
- * *Use the letter of guaranty to verify applicable information.*
- * If no packing material is in use at this time, indicate "none" in item 1 below.
- * Return form in attached envelope.

PLEASE PRINT OR TYPE

1. BRAND NAME OF PACKAGING MATERIAL OR CODE DESIGNATION INDICATED ON LABELING, SHIPPING INVOICE, OR OTHER IDENTIFYING DOCUMENTS (or attach copy of guaranty).

2. NAME AND ADDRESS OF FIRM SUPPLYING PACKAGING MATERIAL (or attach copy of guaranty).

3. NAME OF OFFICIAL THAT SIGNED GUARANTY

4. CHECK ALL CONDITIONS UNDER WHICH THE FOOD PRODUCT(S) IS STORED AFTER IT IS PACKED IN THE PACKAGING MATERIAL

- SAMPLE COPY**
- ☐ a. Hot filled or pasteurized (e.g., 212°F)
 - ☐ b. Boiling water cooked (e.g., 212°F)
 - ☐ c. Hot filled or pasteurized above 150°F
 - ☐ d. Hot filled or pasteurized below 150°F
 - ☐ e. Room temperature filled and stored (no thermal treatment in the container)
 - ☐ f. Refrigerated storage (no thermal treatment in the container)
 - ☐ g. Frozen storage (no thermal treatment in the container)
 - ☐ h. Frozen or refrigerated storage: intended to be reheated or cooked in container at time of use
 - ☐ i. Irradiated in package material
 - ☐ j. Other (describe) _____

5. TYPE(S) OF FOOD PRODUCT(S) PACKAGED IN THIS MATERIAL (e.g., fresh pork, roast beef, giblets, etc.)

6. INSPECTOR NAME (Print or type)	INITIALS	EST. NO.	DATE
-----------------------------------	----------	----------	------

RETURN COMPLETED FORM IN ATTACHED ENVELOPE

If you have any problems or questions, call Compounds and Packaging Branch, PAD, FTS 504-8566. If FTS is not available, call collect (301) 504-8566

FSIS FORM 11,300-11 (3/93)

PREVIOUS EDITION OBSOLETE.

Manager, Establishment #
Establishment Name
Establishment Address
Establishment Address

Date

Dear Establishment Manager:

In accordance with MPI Regulations, Sections 317.24 and 381.144, the Food Safety and Inspection Service (FSIS) monitors the use of food contact packaging materials in official establishments to assure that they conform to the requirements of the Federal Food, Drug, and Cosmetic Act and all applicable food additive regulations. This establishment was selected at random to participate in the monitoring program.

On (Date) , the Federal Inspector at this establishment selected (Material Name) supplied by (Supplier's Name) for review. FSIS has no information on file concerning this packaging material. Therefore, we will need the complete chemical composition and intended use from the supplier in order to ensure that the written guaranty from the supplier listed above can be substantiated.

All major and minor constituents in the formulation must be listed by proper chemical name as they appear in the appropriate regulations (Title 21, Code of Federal Regulations). Dyes and pigments must be identified by their 5-digit Colour Index Constitution number or structural formula. Each ingredient should be further identified by its CAS registry number when available. Chemical formulations and other proprietary information are held in a confidential file and used only to evaluate the material.

Please have your packaging material supplier submit the complete composition of the above material to the address below within 30 days. If the information is not provided within the time indicated, the guaranty will be considered invalid and use of this material in official establishments may be denied.

USDA, FSIS, RP, PAD
Compounds and Packaging Branch
Bldg. 306, BARC-East
Beltsville, Maryland 20705

All correspondence concerning this request must include the monitoring control number below or a copy of this letter.

* (monitoring control #) *

If you have any problems, please call the Compounds and Packaging Branch at (301) 504-8566.

Sincerely,

John M. Damaré, Chief
Compounds and Packaging Branch
Product Assessment Division
Regulatory Programs

cc: Inspector in Charge
Packaging Material Supplier

Manager, Establishment #
Establishment Name
Establishment Address
Establishment Address

F I N A L N O T I C E - (date)

Dear Establishment Manager:

In accordance with MPI Regulations, Sections 317.24 and 381.144, the Food Safety and Inspection Service (FSIS) monitors the use of food contact packaging materials in official establishments to assure that they conform to the requirements of the Federal Food, Drug, and Cosmetic Act and all applicable food additive regulations. This establishment was selected at random to participate in the monitoring program.

On (Date)_____, the Federal Inspector at this establishment selected (Material Name) supplied by (Supplier's Name) for review. FSIS has no information on file concerning this packaging material. Therefore, we will need the complete chemical composition and intended use from the supplier in order to ensure that the written guaranty from the supplier listed above can be substantiated.

All major and minor constituents in the formulation must be listed by proper chemical name as they appear in the appropriate regulations (Title 21, Code of Federal Regulations). Dyes and pigments must be identified by their 5-digit Colour Index Constitution number or structural formula. Each ingredient should be further identified by its CAS registry number when available. Chemical formulations and other proprietary information are held in a confidential file and used only to evaluate the material.

Please have your packaging material supplier submit the complete composition of the above material to the address below within 30 days. If the information is not provided within the time indicated, the guaranty will be considered invalid and use of this material in official establishments may be denied.

USDA, FSIS, RP, PAD
Compounds and Packaging Branch
Bldg. 306, BARC-East
Beltsville, Maryland 20705

All correspondence concerning this request must include the monitoring control number below or a copy of this letter.

* (monitoring control #) *

If you have any problems, please call the Compounds and Packaging Branch at (301) 504-8566.

Sincerely,

Failure to respond to this final notice
within 30 days will result in invalidation
of the guaranty for this material.

John M. Damaré, Chief
Compounds and Packaging Branch
Product Assessment Division
Regulatory Programs

cc: Inspector in Charge
Packaging Material Supplier

FSIS DIRECTIVE

7630.1
Rev. 3

2-3-94

PARTIAL QUALITY CONTROL FOR PROCESSING OPERATIONS

I. PURPOSE

This revised directive provides current FSIS policy and procedures with respect to submittal and routing for approval of new, revised, or amended PQC programs/procedures for processing operations. The list of PQC programs/procedures has been updated and is attached to this directive.

II. CANCELLATION

FSIS Directive 7630.1, Rev. 2, dated 9/6/90

III. REASON FOR REISSUANCE

This directive has been rewritten in its entirety to:

- A. Provide FSIS employees guidance for processing and routing of establishment-submitted proposals for new, revised, or amended PQC programs/procedures;
- B. Update organizational references;
- C. Provide a new FSIS Form 7630-1 (see Attachment 1); and
- D. Update and attach the list of PQC programs (see Attachment 2).

IV. REFERENCES

MPI Regulations, Sections 318.4 and 381.145

V. ABBREVIATIONS AND FORM

AS	Area Supervisor
IIC	Inspector in Charge
PQC	Partial Quality Control
QC	Quality Control
RD	Regional Director

DISTRIBUTION: Inspection Offices,
T/A Inspectors, Plant Management, T/A Plant
Management, TRA, ABB, PRD, AID

OPI: S&T/PPID

S&T Science and Technology
TQC Total Quality Control

FSIS Form 7630-1, TQC/PQC Program Submittal Cover Sheet,
dated 6/93

VI. DEFINITIONS

A. **Voluntary** PQC programs/approved procedures are those elected by the processor; they are not required by FSIS.

B. **Mandatory** PQC programs/approved procedures are required under FSIS regulations to produce certain products or control certain processes.

C. **Conditional** PQC programs/approved procedures are those designed to process products or to control processes in a manner that complies with guidelines, policy memoranda, or other FSIS publications, such as notices or directives.

D. **Approving Authority** will be either the RD or, when specific expertise is needed, S&T, Headquarters, Washington, DC.

VII. GENERAL RESPONSIBILITIES

A. **The Processed Products Inspection Division**, S&T, will continue to issue new, revised, or amended PQC guidelines and policy statements, as needed, and to receive and address technical PQC policy concerns.

B. **Inspection Operations** will receive and address concerns about general operations and administrative responsibilities under a PQC program.

C. The **RD**, in most cases, will be the "Approving Authority" for establishment-proposed new, revised, or amended PQC programs/procedures.

D. **S&T** will be the "Approving Authority" when specific expertise is needed.

VIII. DEVELOPMENT OF PROPOSED PQC PROGRAM/PROCEDURE

A. Upon request by the establishment for information on PQC programs/procedures, the IIC will advise the establishment to contact the Regional QC Specialist. The QC Specialist will furnish the establishment with available PQC information, which includes FSIS regulation requirements, policies and other FSIS material. Guidelines for individual PQC programs/procedures can be obtained through the Area Office.

B. Questions regarding PQC programs/procedures should be directed to the Regional QC Specialist.

C. All new or revised PQC programs/procedures should be accompanied by a cover letter that contains all the information listed below. The cover letter for an amendment to an already approved program/procedure must contain, at a minimum, items "1.," "2.," "3.," and "7." below.

1. Date of submission of documentation.
2. Name of company/establishment, address, telephone number, and establishment number.
3. Objective of the proposed new/revised/amended PQC program/procedure.
4. Length of time data generated by the establishment's proposed or existing PQC program will be retained. Example: "All records generated by this PQC program will be retained a minimum of 1 year."
5. Statement of establishment's commitment to make all data, records, and information generated as a result of the proposed PQC program/procedure readily available to USDA officials.
6. Statement that an assigned, responsible establishment employee will be given authority to halt production and restrict shipment of product if standards established for the program/procedure are not met.
7. Original signature of establishment official responsible for quality control with printed name and title included.

D. Information in the establishment's cover letter shall meet the requirements of MPI regulations, §§ 318.4 and 381.145.

E. All pages and attachments (i.e., required labels, charts, forms, etc.) to the PQC program/procedure are to be numbered.

F. Establishment provides the original to the Regional Office and three copies to the IIC.

IX. APPROVAL PROCESS

A. **The IIC** will initiate and forward FSIS Form 7630-1 to the AS (see Attachment 1). FSIS Form 7630-1 is used to obtain IIC and AS comments to aid the RD in approve/disapprove decisions on establishment-generated proposals for PQC programs or procedures. When completing FSIS Form 7630-1, assure the following steps are taken:

1. Review the proposal, using appropriate guidelines.
2. State, in the "comments" section, the capability of the establishment, including facilities and equipment, to comply with the provisions of the proposed new, revised, or amended PQC program/procedure.
3. Recommend approval or disapproval.
4. Sign.
5. Forward the completed FSIS Form 7630-1 and three copies of the establishment's cover letter and proposal to the AS within 5 working days of receipt.

B. **The AS**, upon receipt of FSIS Form 7630-1 and three copies of the proposal, will:

1. Review the proposal and the IIC's comments.
2. Comment on the same FSIS Form 7630-1 that the IIC made comments on.
3. Sign.
4. Forward the completed FSIS Form 7630-1 and three copies of the establishment's cover letter and proposal to the RD within 5 working days of receipt.

C. **The RD** will, upon receipt of the proposal:

1. Review current FSIS guidelines to determine whether the proposed program/procedure is "voluntary," "mandatory," or "conditional," as defined in Part VI, and whether the "Approving Authority" is the RD or is S&T, Headquarters, Washington, D.C. Examples of proposals requiring S&T approval include those programs/procedures for:

a. Processing shelf stable canned product or perishable, uncured products in hermetically sealed containers. The "Approving Authority" will be the Canning Procedures Branch, Processed Products Inspection Division, S&T.

b. Water re-use. The "Approving Authority" will be the Facilities, Equipment, and Sanitation Division, S&T.

c. Poultry chilling, moisture control, and other similar meat and poultry activities. The "Approving Authority" will be the Slaughter Inspection Standards and Procedures Division, S&T.

2. Forward the following to the S&T division when S&T is the "Approving Authority": the establishment's original cover letter and original proposal, three copies each of the cover letter and the proposal, and the completed FSIS Form 7630-1. Additionally, indicate the RD's recommendation for approval or rejection.

D. **The RD will:**

1. When "Approving Authority," evaluate the proposal and the comments received on FSIS Form 7630-1 and, if the proposal is satisfactory, approve it according to directions given in IX.F. below.

a. File the original documents comprising the complete record in the Regional Office in chronological (date) order.

b. Forward copies of the complete record to the AS and the IIC for filing in chronological (date) order.

2. When not "Approving Authority," discuss information received on FSIS Form 7630-1 with the "Approving Authority" in S&T.

E. **S&T division**, when "Approving Authority" because of expertise in the subject-matter area, will review the proposal provided by the RD, using information provided by the RD, MPI Regulations, §§ 318.4 and 381.145, and other appropriate guidelines. The approval process will proceed as detailed in IX.F. below.

1. Return the original submittal to the Regional Office for filing in chronological (date) order as part of the complete record.

2. Forward copies of the complete record to the AS and the IIC for filing in chronological (date) order.

NOTE: The "complete record" referred to in IX.D.1. and IX.E.1. and 2. consists of the original incoming cover letter from the establishment; the original of the proposal stamped on every page with the word, "APPROVED," and with the date of approval; and a copy of the notification of approval.

F. **Either the RD or S&T**, when "Approving Authority," will:

1. Approve any proposal **without revisions**, where possible.

a. Stamp each page of the proposed new, revised, or amended PQC program/procedure with the word "APPROVED" and the date of approval.

b. Prepare and send a letter to establishment management stating that the proposal has been approved. Attach a copy of the proposal with the stamp of approval and date of approval on every page.

2. Approve any proposal with **minor changes**:

a. Contact the IIC and/or establishment management directly to discuss needed changes.

b. Ensure that the establishment provides copies of corrected pages for the proposal, through the IIC, unless otherwise directed.

c. Make judicious use of pen and ink changes, if agreed on by establishment management.

d. Continue with the approval process as described above in Paragraph IX.D.1.

3. Deny any proposal that needs **extensive revision** and provide formal notification to the applicant with copies to the AS and the IIC:

a. Detail the basis for denial, as required by MPI Regulations, §§ 318.4 and 381.145.

b. Request that the establishment submit any revisions directly to the "Approving Authority" and provide the name and address of the person to whom the revisions should be sent.

c. Attach and return the original to the establishment with copies of the letter to the AS and IIC.

NOTE: Proposed PQC programs/procedures being either approved or denied should **not** be returned to the establishment management by any level except the "Approving Authority."

G. **The RD, the AS and the IIC** should be careful when inserting approved revised pages in all existing copies of a proposal or of an already approved program/procedure.

1. Insert pages with changed wording. Check continuity of text from prior pages. Destroy voided pages.

2. Ensure:

a. Accuracy of the original/copies;

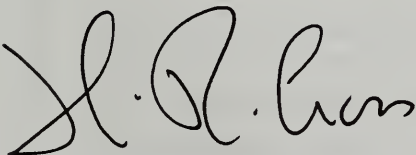
b. Maintenance of confidentiality of establishment data;

c. Uniformity of file contents; i.e., the files contain the complete "package" and are filed in chronological (date) order; and

d. Approval information is entered in the RD's QCSYSTEM database and, once in the regional system, is transmitted to the Headquarters QCSYSTEM database.

X. TERMINATION OF A PQC PROGRAM/PROCEDURE

An approved PQC program may be terminated at any time by the owner or operator of the establishment upon written notice to the RD. The RD shall respond in writing to the establishment official and provide copies of the rescindment letter to the IIC and AS.



Administrator

Attachments

1--FSIS Form 7630-1

2--Lists of PQC Programs/Procedures

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INSPECTION OPERATIONS

TQC / PQC PROGRAM SUBMITTAL COVER SHEET

INSTRUCTIONS: Please complete all applicable items. Include any additional comments or information that should be considered by the approving office.

(Check one)

- ☐ TOTAL QUALITY CONTROL SYSTEM (TQCS)
- ☐ PARTIAL QUALITY CONTROL PROGRAM (PQCP) (Indicate the type of program being applied for in the Plant Information section below.)
- ☐ PROCESSING PROCEDURE (Indicate the type of procedure being applied for in the Plant Information section below.)

EST. NO.	P -	NAME OF IIC (Please print)	NAME OF CIRCUIT SUPERVISOR (Please print)
NAME OF AREA OFFICE		AREA / CIRCUIT NO.	NAME OF AREA SUPERVISOR (Please print)

PLANT INFORMATION

NAME OF PLANT

ADDRESS: (Street)

(City, State and Zip Code)

DATE IIC RECEIVED REQUEST FROM PLANT	(Check one) <input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT <input type="checkbox"/> REVISION	DATE ON PLANT'S COVER LETTER
--------------------------------------	--	------------------------------

TYPE OF PROGRAM / PROCEDURE BEING SUBMITTED FOR: (Be specific: Note FSIS Directive 7630.1, Rev. 3)

PQC / PROCEDURE NO.	DESCRIPTION
---------------------	-------------

IIC RECOMMENDATION

- ☐ APPROVE - No additional comments ☐ DISAPPROVE - Reasons specified under comments
- ☐ APPROVE - With comments ☐ OTHER - Explanation given under comments

COMMENTS: (If needed, use reverse or attach a separate sheet.)

SIGNATURE OF INSPECTOR-IN-CHARGE	Program/Procedure must be reviewed and forwarded to Area Supervisor within 5 working days of date IIC receives proposal from plant.	DATE FORWARDED TO AREA SUPERVISOR
----------------------------------	---	-----------------------------------

AREA SUPERVISOR'S RECOMMENDATION

- ☐ APPROVE - No additional comments ☐ DISAPPROVE - Reasons specified under comments
- ☐ APPROVE - With comments ☐ OTHER - Explanation given under comments

COMMENTS: (If needed, use reverse or attach a separate sheet.)

SIGNATURE OF AREA SUPERVISOR	Program/procedure must be reviewed and forwarded to Regional Office within 5 working days of date Area Supervisor receives recommendations from IIC.	DATE FORWARDED TO REGIONAL OFFICE
------------------------------	--	-----------------------------------

FSIS FORM 7630-1 (6/93)



FSIS DIRECTIVE 7630.1
Revision 3
Attachment 2

LISTS OF PQC PROGRAMS AND APPROVED PROCEDURES

I. List of PQC Programs:

NO.	TITLE AND DEFINITION
110	<u>Weight Control</u> means the control of net weight, fill weight and drained weight of a product. The weight may be controlled and monitored by any statistically sound and documentable method. [Formerly titled "Net Weight."] Voluntary. Regional approval.
115 New	<u>Scale Self-Certification</u> means the documented procedure for the testing of scales to assure they meet all accuracy requirements specified in the NIST Handbook 44. Voluntary. Washington approval.
120	[Was "Drained Weight"; now in 110, "Weight Control."]
130	[Was "Fill Weight"; now in 110, "Weight Control."]
140	[Changed to 142.]
142	<u>Trichinae Control by Process</u> means the control of trichinae by heating, refrigerating, curing, or drying. Voluntary. Regional approval.
215	<u>Mechanically Separated (Species) Product(s)</u> means the control of meat product(s) obtained mechanically from beef, pork, sheep, goats, or equine bones. Mandatory. Regional approval.
220	<u>Microbiological Control and Monitoring Program</u> in a heat processed product department is an alternative to a thorough mid-shift cleanup. This includes the documented procedures for controlling, preventing, or correcting sanitation deficiencies and the documented procedures for organoleptic and laboratory evaluation of the sanitation deficiencies. Conditional. Regional approval.
224	<u>Water Reuse</u> includes the documented procedures for utilizing water based fluids for more than one product or equipment exposure. Conditional. Washington approval.
225	<u>Mechanically Separated Poultry Product</u> means the control of poultry meat product obtained mechanically from poultry bones. Voluntary. Regional approval.
230	<u>Pork Skins for Popping</u> means checking for hair roots prior to or after popping of pork skins. Voluntary. Regional approval.

NO.	TITLE AND DEFINITION
245	[Was "Returned Product"; now in 840, "Miscellaneous Control."]
250	<u>Flexible and Semirigid Retortable Packages</u> means the approved thermal processing schedules; product process procedures; and procedures for maintaining package integrity. Limited to product covered by the canning regulations and packed in flexible or semirigid containers. Conditional. Washington approval.
255	<u>Aseptically Processed Products</u> means the control of aseptic processing and packaging systems to produce thermally processed, shelf stable product (i.e., subject to canning regulations). Mandatory. Washington approval.
270	<u>Foreign Material</u> means the identification, restraint, and disposition of product containing materials such as metal, plastic, rubber, or glass. Voluntary. Regional approval.
290	<u>Boneless Meat Reinspection</u> means to identify, classify, and control Acceptable Quality Levels for defects in boneless meats for manufacturing. Voluntary. Regional approval.
295 New	<u>Air/Gas Injection</u> means the documented procedure for injecting air or compressed gas (carbon dioxide) into carcasses or carcass parts during the boning operation to facilitate boning. Conditional. Washington approval.
310	<u>Vignette Labeling</u> means the control used to verify the product complies with the quality or product characteristics shown by the graphic display on the label. Voluntary. Regional approval.
320	<u>Declared Count Labeling</u> means the control used to verify label statements showing units of product in the container, either by actual count, range, minimum count, or by group of units. Must be accomplished by statistically sound methods. Voluntary. Regional approval.
345	[Eliminated.]
350	[Was "Combination Meats Formulation Control" now in 690, "Percent Labeling Control."]
355	<u>Raw Product Fat and Moisture Control</u> means the documented procedure to ensure product compliance with maximum limitations on fat and added water. Voluntary. Regional approval.

FSIS DIRECTIVE 7630.1
Revision 3
Attachment 2

NO.	TITLE AND DEFINITION
360	<u>Ground Beef Fat Control</u> means the control of blending and control of analytical fat in finished uncooked chopped or ground beef. Voluntary. Regional approval.
370	<u>Fresh Pork Sausage Fat and Moisture</u> means the control of analytical fat of the sausage and the amount of added water used in the formulation. Voluntary. Regional approval.
385 New	<u>Injection of Suspensions of Ground Trimmings into Ham/Poultry/Roast Beef Products</u> means to control the manufacturing of boneless ham, poultry products, or roast beef products. Conditional. Regional Approval.
393	[Now in 396.]
396 New	<u>Addition of a Solution to Cooked Beef/Roast Beef</u> means to control the pumping and/or the massaging procedures, and yield of roast beef/cooked beef to ensure that the label declaration for added substances is accurate. [Note: PQC programs 393 and 397 were combined into this.] Conditional. Regional approval.
397	[Now 396.]
398	<u>Pumped Corned Beef</u> means to control the pumping procedures in corned beef to ensure that the label declaration for added substances is accurate. Conditional. Regional approval.
402	<u>Addition of Solution to Cooked Corned Beef</u> means to control the pumping and/or the massaging procedures and yield of corned beef to ensure that the label declaration for added substances is accurate. Conditional. Regional approval.
403	[Was "Addition of Solution of Ascorbic Acid, Citric Acid, Erythorbic Acid, Sodium Ascorbate, and Sodium Citrate (singly or in combination) to Fresh Pork Cuts"; now in 840, "Miscellaneous Control."]
404	<u>Addition of Solution to Pork Products</u> means to control the pumping, the massaging, procedures and/or yield in pork products to ensure that the label declaration for added substances is accurate. Conditional. Regional approval.

NO.	TITLE AND DEFINITION
405	<u>Water-Misted/Ice-Glazed Meat and Poultry Products</u> means the documented control procedures to demonstrate that a fine water mist or ice-glaze applied to a meat or poultry product is sublimed when the product is frozen. Conditional. Regional approval.
430	<u>Batter and Breading</u> means to control the amount of batter and/or breading applied as a coating around the product. Voluntary. Regional approval.
440	<u>Basting/Marination</u> means the control of functional substances injected or soaked into poultry, not in excess of 3% (bone-in) or 8% (boned). Mandatory for basted product; Conditional for marinated product. Regional approval.
442	<u>Marination of Red Meat</u> means the control of substances injected or soaked into red meat. Conditional. Regional approval.
450	[Was "Pumped Poultry"; now in 455.]
455	<u>Addition of Solution to Poultry</u> means the control of added substances absorbed by poultry in excess of limits for marination. Conditional. Regional approval.
460	<u>Cooked Meat Substitution</u> means the controlled use of cooked meat in place of fresh or uncooked meat. Conditional. Regional approval.
480	<u>Tenderizer Pickup</u> means the control of the process to assure addition of proteolytic enzyme(s) and carrier does not exceed 3% of the product weight. Voluntary. Regional approval.
501 New	<u>Irradiation Processing Control</u> means the control of irradiation processing of fresh or frozen uncooked whole poultry carcasses or parts. Mandatory. Washington approval.
502 New	<u>Irradiation Control of Products To Be Irradiated</u> means the control of pre-labeled (irradiated) fresh or frozen uncooked whole poultry carcasses or parts shipped to an official irradiation facility to be irradiated. Mandatory. Washington approval.
520	<u>Cooked Sausage Fat and Added Water</u> means the control of maximum permissible fat and added water in the finished product by controlling raw product, blending, formulation, cooking (smoking), and chilling. Voluntary. Regional approval.

FSIS DIRECTIVE 7630.1
Revision 3
Attachment 2

NO.	TITLE AND DEFINITION
540	<u>Minimum Meat Content Control</u> means the control of the meat ingredient by weighing the quantity of meat in the formulation; weighing the washed and drained weight of the meat; or weighing the quantity of meat in finished product to meet minimum USDA meat requirements. Voluntary. Regional approval.
550	<u>FNS Labeling and Non-Meat Labeling Control</u> means the control of fat, formulation, yield, portion weights, component weights, and other label requirements. Conditional. Regional approval.
565	[Was "Percent Meat Washout"; now 540, "Minimum Meat Content Control."]
670	<u>Dry Sausage Moisture/Protein Ratio</u> means control of formulation, fermentation process and analyses for moisture and protein of the finished product. Voluntary. Regional approval.
690	<u>Percent Labeling Control</u> means the documented procedure to verify labeling claims for stated weights of ingredients or components in a product. Conditional. Regional approval.
695	[Was "Percent Labeling Ingredient Weight Control"; now in 690, "Percent Labeling Control."]
720	<u>Turkey Ham Control</u> means the control of the processing and yield of cured turkey thigh meat. Voluntary. Regional approval.
725	<u>Turkey Ham and Water Products - X% Yield Control</u> means the control of added ingredients in turkey ham. The yield may be monitored by any means that is documentable and ensures that the X% is no more than is declared on the label claim. Conditional. Regional approval.
740	<u>Precooked Breakfast Sausage Yield Control</u> means the amount of sausage expressed on the basis of the fresh uncooked sausage. Voluntary. Regional approval.
770	<u>Low Temperature Rendering</u> means the control of by-products derived from rendering beef or pork tissue at 120°F. or less. Documented procedures for determining compliance with raw material requirements, i.e., 12% lean, are included. Voluntary. Regional approval.

NO.	TITLE AND DEFINITION
772	<u>Chemical Analysis in Lieu of the Knife Trim Test</u> means the control of beef and pork trimmings such that chemical analysis can be substituted for the knife trim test in determining when trimmings contain at least 12% separable lean. Voluntary. Regional approval.
775	<u>Low Temperature Rendering for Export to Japan</u> means the control of by-products derived from rendering partially defatted beef fatty tissue at 120°F. or less, for shipment to Japan. Documented procedures for determining compliance with raw material requirements, i.e., 5% or less muscle meat, are included. Conditional. Regional approval.
776 New	<u>Fat-Reduced Control</u> means the processing controls for manufacturing fat-reduced (species)--FR(S)--from beef and pork fatty tissue and the analytical limits of the finished product. Conditional. Washington approval.
780	[Was "High Temperature Rendering"; now 840, "Miscellaneous Control."]
815	<u>PFF Added Substance Control</u> means the control of the protein fat free portion of a cured pork product to ensure the PFF content is in compliance with the standards. Voluntary. Regional approval.
823	<u>Dry Cured Products</u> means the control of pork products produced by rubbing the external meat surface with curing ingredients to meet requirements in 9 CFR Part 319. Voluntary. Regional approval.
825	<u>Cured Pork Products--Control of X% Added Ingredients</u> means the control of the added ingredients in a cured pork product for which a PFF standard has not been established. The yield (X%) may be controlled by any means which is documentable and ensures the X% is no more than is declared on the label. Mandatory. Regional approval.
833	<u>Finished Product Inspection</u> means procedures to ensure compliance with any or all of the requirements of 9 CFR 318.309 or 9 CFR 381.309 including incubation testing, condition-of-container examinations, and the handling of abnormal containers/affected production. Voluntary. Washington approval.
835	<u>Retort Equipment Control</u> means the method used to ensure that retort equipment is adequately equipped, instrumented, maintained, and operated to deliver an adequate process to thermally processed products. Voluntary. Washington approval.

FSIS DIRECTIVE 7630.1
Revision 3
Attachment 2

NO.	TITLE AND DEFINITION
840	<u>Miscellaneous Control</u> means the documented program for controlling specific or unique requirements that are unique to limited situations. <u>Voluntary/Conditional/Mandatory. Regional approval.</u>
845	<u>Process Deviation Control for Canned Product</u> means the procedures developed by canning establishments for the handling of process deviations and control of the affected product. Programs are designed to significantly reduce official retention of product and the need to handle deviations in accordance with 9 CFR 318.308 or 9 CFR 381.308. <u>Voluntary. Washington approval.</u>
847	<u>Hermetically Sealed Container Cooling Water Reuse</u> means the documented procedures for maintaining the quality of reused container cooling water. <u>Voluntary. Washington approval.</u>
850	<u>Perishable, Uncured Meat and Poultry Products in Hermetically Sealed Containers</u> means products that: receive a heat treatment not sufficient to yield a shelf stable product; are packed in airtight containers such as glass jars, metal cans, flexible pouches, and plastic trays, bowls and cups; and bear a "keep-refrigerated" or similar label statement. <u>Conditional. Washington approval.</u>
880	[Was "Meat Content"; now 540, "Minimum Meat Content Control".]
895	[Was "Precooked Products Yield Control"; now 840 "Miscellaneous Control."]
900	[Was "Bacon Yield Control"; now 840, "Miscellaneous Control."]
905	[Was "Broiled Beef Patties Yield Control"; now 840, "Miscellaneous Control."]
920	[Was "Restructured Meat Control"; now in 840, "Miscellaneous Control."]
925	[Was "Formulated Bacon" now in 840, "Miscellaneous Control."]

NO.	TITLE AND DEFINITION
927	<u>Bacon With Up To 120 ppm Nitrite</u> means the control of the in-going nitrite, ascorbate, and other mandatory ingredients in the preparation of bacon. Voluntary for 120 ppm nitrite; Mandatory for less than 120 ppm nitrite. Regional approval.

II. List of Approved PQC Procedures:

260	<u>Foreign Material</u> means the identification, restraint, and disposition of product containing materials such as metal, plastic, rubber, or glass (FSIS Directive 7310.4). Conditional. Regional approval.
280	<u>Boneless Meat Reinspection</u> means the identification, classification, and control of Acceptable Quality Levels for defects in on-line boneless meat manufacturing. Voluntary. Regional approval.
330	<u>Product Identification Labeling</u> means the control used to verify the label claims pertaining to the source material. Conditional. Regional approval.
345	<u>Nutritional Labeling Verification</u> means the verification of the accuracy of nutritional information declared on the label. Conditional. Regional approval.
380	<u>Time/Temperature Process Control</u> means the control of the time and temperature process used for any non-hermetically sealed meat product. Voluntary. Regional approval.
390	<u>Roast Beef for Processing Control</u> means the documented processing procedure for control of ingredients, time/temperature, and other requirements of 9 CFR 318.17. Mandatory. Regional approval.
395	<u>Cooked Beef for Processing Control</u> means the documented processing procedure for control of time, temperature, humidity, cooling, handling and other requirements of 9 CFR 318.17. Mandatory. Regional approval.
400	<u>Cooked Corned Beef for Processing Control</u> means the documented processing procedure for control of time, temperature, humidity, cooling, handling and other requirements of 9 CFR 318.17. Mandatory. Regional approval.

FSIS DIRECTIVE 7630.1
Revision 3
Attachment 2

640	<u>Pickling/pH Control</u> means the procedures used to produce shelf stable products by controlling the pH of the finished product at 4.6 or lower through addition of vinegar or other approved acidulants, such as citric acid. Such products may contain other approved ingredients but are NOT heat processed. Voluntary. Regional approval.
680	<u>Grade Labeling</u> means the control of officially graded product which is further processed and labeled with official grades. Conditional. Regional approval.
750	<u>Cooked Poultry Cooling</u> means procedures used to handle and cool cooked poultry (carcass, halves, parts) to prescribed time/temperature relationships. Voluntary. Regional approval.
830	<u>Miscellaneous Procedure Control</u> means the documented procedure for controlling specific requirements that are unique to limited situations. Mandatory/Voluntary/Conditional. Regional approval.

215 1975
0538
1992

FSIS DIRECTIVE

8091.1

10/22/01

PROCEDURES FOR THE FSIS HEALTH HAZARD EVALUATION BOARD

I. PURPOSE

This directive explains the duties of the FSIS Health Hazard Evaluation Board (HHEB) and the procedures the HHEB follows when evaluating meat, poultry, and egg products to determine whether their consumption may pose a human health risk.

II. CANCELLATION

FSIS Directive 10,530.3, Contamination Response System (CRS) dated 3/23/93.

III. [RESERVED]

IV. REFERENCES

The Meat, Poultry, and Egg Products Inspection Regulations.

FSIS Directive 8080.1, Revision 3 - Recall of Meat and Poultry Products.

V. POLICY

Under the HACCP system regulations at 9 CFR § 417.1, a food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption. Biological hazards are infectious agents (including living organisms and prion proteins) that can make food unsafe to eat. Chemical hazards can be either naturally-occurring or added. Physical hazards are extraneous materials that are not expected in a food that may cause illness or injury.

VI. What is the HHEB and what is its purpose?

A. The HHEB will be the primary group that reviews the public health significance of any human health hazard about which a regulatory decision needs to be made by the Agency.

B. The purpose of the HHEB is twofold. First, when there is reason to be concerned, but no definitive determination, as to whether a product that is about to enter or has entered commerce may be injurious to health, the HHEB would be called upon to assess the nature and severity of the hazard and to provide information to the Agency for an Agency decision on regulatory action, (e.g., withhold the marks of inspection, request a recall, detention or seizure of product). Second, the HHEB would be called upon in other than emergent situations to provide an assessment of product safety (e.g., an assessment regarding the toxicity of a foreign material found in product). The HHEB does not decide on or recommend regulatory or other action but provides information for such decisions or recommendations.

C. The HHEB will rapidly communicate information from its meetings concerning a human health hazard to the Deputy Administrator, Office of Public Health and Science (see section X of this Directive).

VII. Who comprises and leads the HHEB?

A. The HHEB is an ad hoc committee composed of representatives from various offices within FSIS. The Director of the Human Health Sciences Division (HHSD), Office of Public Health and Science (OPHS), at the request of the Administrator, Associate Administrator, or any Deputy Administrator, convenes and chairs the HHEB. The HHEB may include physicians, health scientists, microbiologists, toxicologists, veterinarians, chemists, program analysts, epidemiologists, food technologists, and other relevant experts from within FSIS.

B. The minimum membership of the HHEB will include one physician, one epidemiologist, and one representative from the Office of Policy, Program Development and Evaluation.

C. Other government (either Federal or State) experts from outside FSIS or one non-governmental expert (for example from academia, non-governmental scientists, public health experts or from industry that is not tied to the specific problem) may also be called to participate, when appropriate.

VIII. When is the HHEB convened?

A. The HHEB is convened at the request of the Administrator, Associate Administrator, or any Deputy Administrator when the Agency is presented with a situation in which a human health hazard needs to be evaluated. The need may be raised by the FSIS Administrator; FSIS staff members, including the Technical Service Center and Field Operations Staff; the FSIS Recall Committee; or industry. The official requesting the HHEB will provide the chair of the HHEB with a written statement of the human health impact assessment needed for an Agency decision.

B. The HHEB does not meet on matters that are covered by an existing Agency precedent (e.g., an FSIS regulation). However, an appropriately empowered Agency official (the Administrator, Associate Administrator, or any Deputy Administrator) may decide that it is appropriate to have the HHEB reconsider an existing precedent.

C. Decisions of the HHEB on the nature and severity of a hazard or the safety of a product will be made on a consensus basis. (Consensus is to be among the members of the HHEB with a scientific background.)

IX. How does the HHEB conduct its evaluations?

A. When the HHEB conducts an evaluation of a health hazard that may be presented by a product, it will assess:

1. any disease or injuries that have already occurred from the ingestion of the product.
2. the potential health hazard to relevant segments of the population, including children, immuno-compromised persons, or the elderly who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.
3. the degree of seriousness of the health hazard to which the populations at risk would be exposed.
4. the likelihood of occurrence of the hazard.
5. the consequences (immediate or long-range) of occurrence of the hazard.

NOTE: It is not the purpose of the HHEB to duplicate the processes of the Recall Committee, nor is it the purpose of the HHEB to participate in every meeting associated with every potential food product recall.

X. How and to whom will the HHEB report its findings?

The HHEB provides a concise written summary of its deliberations, signed by the Chair (with members listed), to the Deputy Administrator, OPHS. Supporting documentation is submitted as appendices to the summary if needed. The Deputy Administrator, OPHS, will provide the written summary to the appropriate decision-maker, (e.g., Administrator, Associate Administrator, or Deputy Administrator) for consideration.



Deputy Administrator
Office of Policy, Program Development
And Evaluation

United States Department of Agriculture
Food Safety and Inspection Service
5601 Sunnyside Avenue, Mail Drop 5241
Beltsville, MD 20705-5241

OFFICIAL BUSINESS
Penalty for Private Use, \$300

FIRST-CLASS MAIL
POSTAGE & FEES PAID
USDA-FSIS
Permit No. G-42

FSIS DIRECTIVE

9040.1
Rev. 2

8/12/93

REINSPECTION OF PRODUCT INTENDED FOR EXPORT

I. PURPOSE

This directive provides responsibilities and procedures for reinspecting and certifying product for export. These responsibilities and procedures apply whether the product is located at the establishment where produced, or off site, such as in a cold storage facility.

II. CANCELLATION

FSIS Directive 9040.1, Revision 1, dated 10/20/86.

III. REASON FOR REISSUANCE

These procedures have been revised to eliminate the requirement that cartons intended for export be opened and the product observed by the inspector if visual examination of the lot shows no signs of damage from product handling or storage. For this reason, this directive has been rewritten. This directive will remain in force until the Export Certification Information System is implemented by International Programs.

IV. REFERENCES

MPI Regulations, Sections 318.2, 322.2 and 381.105
FSIS Directive 7520.2, dated 5/12/88 and Amend. 1, dated 9/8/88
FSIS Directive 9020.1, dated 5/15/84

V. POLICY

Exporters requesting USDA certification for product intended for export must agree prior to the certification that the product will be subject to reinspection before being exported, so that the product's identity and eligibility for export may be determined. FSIS may perform more in-depth reinspection procedures at any time in response to complaints from countries receiving United States product.

VI. RESPONSIBILITIES

A. The exporter must:

1. Complete FSIS Form 9060-6, Application for Export, to request product reinspection and certification for export, and
2. Arrange for the inspector to reinspect the lot and, if the inspector determines it is necessary, remove those samples, as directed by the inspector, from the lot.

B. For reinspection purposes, a "lot" of meat or poultry must represent only one type of product and originate from one establishment. It may, however, consist of different sizes of the same item.

C. The inspector will:

1. Assure that all products meet MPI Regulations and importing countries' requirements, and
2. Perform a sensory evaluation of the lot, as specified in Paragraph VII of this directive, prior to certification, to determine the lot's eligibility for export. The inspector should be particularly alert for signs of off-condition product or evidence of improper handling or storage.

VII. INSPECTION PROCEDURES

A. Fresh Meat and Poultry Products (Frozen and Unfrozen) and Processed Meat and Poultry Products

1. When certifying inspected and passed fresh meat and poultry products (frozen and unfrozen) or processed meat and poultry products for export, the inspector will organoleptically examine shipping cartons in the lot for signs of poor product handling and storage (e.g., torn, damp or damaged cartons; off-condition odor).

2. If the lot **DOES NOT** show signs of poor product handling and storage, the shipping cartons will be stamped with the export mark and FSIS Form 9060-5, Meat and Poultry Export Certificate of Wholesomeness, will be issued.

3. If the lot **DOES** show signs of poor product handling and storage, the inspector will:

- a. open a maximum of 10 affected shipping cartons,
- b. if frozen, temper or thaw all individual packages in the carton, and
- c. check the product for soundness and wholesomeness.

4. Certain products must be handled as follows:

- a. Bulk-packed products such as pork livers, boneless beef, poultry giblets and fat must be completely defrosted or a sample unit cut from the center of the product and completely defrosted.
- b. Whole poultry carcasses, poultry parts or tray packs must be sufficiently tempered to allow for examination.

5. If the product is found to be sound and wholesome, the inspector will allow repackaging of all affected cartons, at the packer's option. Repackaging will be done under Inspection Operations (IO) program supervision under the provisions of FSIS's voluntary Identification Service, at the packer's cost. Following repackaging, the establishment should stamp the shipping cartons with the export mark.

6. If the product is **NOT** sound or wholesome, the inspector will retain the lot and notify the IO supervisor.

B. Canned Product

1. When certifying inspected and passed canned product for export, the inspector will visually examine all shipping cartons in the lot for signs of poor product handling and storage (e.g., torn, damp, or damaged shipping cartons/immediate containers).

2. If the lot **DOES NOT** show signs of poor product handling and storage, the shipping cartons will be stamped with the export mark and FSIS Form 9060-5, Meat and Poultry Export Certificate of Wholesomeness, will be issued.

3. If the lot **DOES** show signs of poor product handling and storage, a condition of container examination will be performed by the inspector in accordance with FSIS Directive 7520.2, Amend. 1, dated 9/8/88, and as directed by the IO supervisor.

VIII. QUESTIONS

Questions regarding export certification procedures should be referred to the Export Coordination Division, International Programs, (202) 720-9051.

Craig A. Seed

Deputy Administrator
Inspection Operations

page 4

United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C.
20250

OFFICIAL BUSINESS
Penalty for Private Use, \$300

MAILED AT
BALTIMORE, MD
DROP SHIPMENT
AUTHORIZATION 26
PRESORTED FIRST-CLASS



FIRST CLASS MAIL

37/403MPSLD1594 R1 103-0001
E2

US DEPT OF AGRICULTURE
FOOD & NUTRI INFORMATION CNTR
NAT'L AGRI LIBRARY, RM 304
BELTSVILLE MD 20705-2351

FSIS DIRECTIVE10,010.1,
Revision 1

3/31/04

**MICROBIOLOGICAL TESTING PROGRAM AND OTHER VERIFICATION ACTIVITIES
FOR *Escherichia coli* O157:H7 IN RAW GROUND BEEF PRODUCTS AND RAW
GROUND BEEF COMPONENTS AND BEEF PATTY COMPONENTS**

**NOTE: FSIS PERSONNEL ARE NOT TO IMPLEMENT THIS DIRECTIVE UNTIL
MAY 17, 2004**

Part I – General**I. PURPOSE**

This directive provides Food Safety and Inspection Service (FSIS) inspection program personnel, program investigators, and import inspection personnel instructions for sampling raw beef products as part of verification testing for *Escherichia coli* O157:H7 (*E. coli* O157:H7) to ensure the protection of public health. It also outlines actions FSIS will take when a raw ground beef product sample, raw ground beef component sample, or raw beef patty component sample is found to be positive for *E. coli* O157:H7. Attachment 1 provides questions and answers for further clarification.

II. CANCELLATION

FSIS Directive 10,010.1, dated 2/1/98
FSIS Notice 11-03, dated 4/18/03
FSIS Notice 47-02, dated 11/20/02

III. REASONS FOR REISSUANCE

This directive has been rewritten in its entirety to be consistent with the Agency's current policies regarding *E. coli* O157:H7. No establishment that produces raw ground beef products, raw ground beef components, or raw beef patty components will be exempt from FSIS sampling and testing for *E. coli* O157:H7. This directive provides new instructions: 1) for the policy that non-intact raw beef products contaminated with *E. coli* O157:H7 are adulterated; 2) for follow-up actions taken after an initial FSIS sample tests positive; and 3) for verifying the control of beef products that are presumptive positive or positive for *E. coli* O157:H7.

IV. REFERENCES

Federal Meat Inspection Act
9 CFR 318.2, 325.10, 416, 417, and 500
FSIS Directives 5000.1, Revision 1, 5000.2, and 8080.1, Revision 3
Federal Register Notices: Policy on Beef Products Contaminated with *E. coli* O157:H7 (64 FR 2803, 1/19/99); Recent Developments Regarding Beef Products Contaminated with *Escherichia coli* O157:H7; Public Meeting (65 FR 6881, 2/11/00); Availability of and Request for Comment on FSIS Draft Risk Assessment for *Escherichia coli* O157:H7 in Ground Beef (66 FR 55912, 11/05/01); and *E. coli* O157:H7 Contamination of Beef Products (67 FR 62325, 10/7/02).

V. BACKGROUND

Non-intact raw beef products contaminated with *E. coli* O157:H7 are adulterated. Non-intact beef products include ground beef; beef that has been injected with solutions; beef that has been mechanically tenderized by needling, cubing, Frenching, or pounding devices; and beef that has been reconstructed into formed entrees. Intact raw beef products contaminated with *E. coli* O157:H7 that are intended to be processed into non-intact products are also adulterated. Establishment records and HACCP documents (e.g., the flow chart and hazard analysis) should identify the intended use of intact raw beef products. Manufacturing trimmings (e.g., pieces of meat remaining after steaks, roasts, and other intact cuts are removed) are an example of intact raw beef product that may be intended to be used for non-intact product. Raw beef products contaminated with *E. coli* O157:H7 may, however, be further processed at official establishments to destroy the pathogen.

On October 7, 2002, FSIS published a notice requiring establishments that had not already reassessed their Hazard Analysis and Critical Control Point (HACCP) plans for raw beef products in light of relevant *E. coli* O157:H7 data to do so to determine whether *E. coli* O157:H7 contamination was reasonably likely to occur in their production process for raw beef products (67 FR 62329). In that notice, FSIS advised that it intended to scrutinize very closely the hazard analyses and HACCP plans of those slaughter or deboning establishments that had conducted a reassessment and decided that an intervention was not necessary. Also in that notice, FSIS stated that establishments receiving product for grinding should address *E. coli* O157:H7. FSIS explained that these establishments could employ validated Critical Control Points (CCPs) in their HACCP plans to address *E. coli* O157:H7, or the establishments could incorporate purchase specifications in their HACCP plans, Sanitation Standard Operating Procedures (Sanitation SOPs), or other prerequisite programs to prevent *E. coli* O157:H7-contaminated product from entering their establishments.

This directive focuses on raw ground beef products and the beef products that are used to produce raw ground beef products. These products will be the focus of FSIS' verification sampling program for *E. coli* O157:H7. Products that FSIS may sample are listed in Parts II and VI.

This directive discusses the significance of a finding that a sample is "presumptive positive." A sample is presumptive positive when analytical steps of microbiological analysis indicate the strong possibility that *E. coli* O157:H7 is present, but additional steps are needed to confirm the presence or absence of the organism.

A sample is confirmed to contain the bacterial isolate of *E. coli* O157:H7 through testing by either FSIS or non-FSIS laboratories when biochemical, serological, or genetic testing results in a finding of *E. coli* Serotype O157:H7, O157:H7:NM (nonmotile), or O157:H7-indeterminate.

FSIS recognizes that many establishments test their raw ground beef products, raw ground beef components, and raw beef patty components for *E. coli* O157:H7. The Agency applauds and encourages this practice. FSIS points out, however, that if an establishment finds a sample of one of these products to be presumptive positive for *E. coli* O157:H7, that product would only be allowed to move off site under appropriate controls for proper disposition at official establishments, landfill operations, or renderers. If the establishment's confirmation testing finds the sample negative for the pathogen, that product may be shipped in commerce under normal procedures. Product that is confirmed positive for *E. coli* O157:H7, through FSIS or establishment testing, may also be moved off site under appropriate controls for proper disposition. If product is confirmed positive, or is presumptive positive and no additional testing confirmed the product negative, such product destined for an official establishment for further processing that will destroy the pathogen would have to move under company control (e.g., through company seals) or under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1). Such product destined for a landfill operation or renderer would have to move under company control.

According to 9 CFR 325.10, if product is found to be adulterated or misbranded after it has been transported from an official establishment, transportation back to the establishment that originally produced the product or to another official establishment must be authorized. According to 9 CFR 318.2(d), inspection program personnel must place a U.S. retained tag at the time of reinspection on all products suspected of being adulterated. FSIS will allow product that is positive or presumptive positive for *E. coli* O157:H7 to move under company control (e.g., through company seals) or under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1), rather than as required in 9 CFR 325.10 and 318.2(d) to facilitate proper disposition of product that may be adulterated with *E. coli* O157:H7. FSIS intends to modify these regulations to reflect this policy.

Part II -- Inspection Program Personnel Responsibilities for Collecting Raw Ground Beef Product Samples from Official Establishments

A. What comprises raw ground beef products?

Raw Ground Beef Products: Raw ground or chopped beef, hamburger, ground or chopped veal, veal or beef patties, and patty mix. A raw ground beef product that contains any amount of beef product derived from advanced meat recovery (AMR) systems is considered a raw ground beef product. Raw product comprised only of beef from AMR systems is not considered a raw ground beef product. Raw product comprised only of beef from AMR systems is considered a raw ground beef component or raw beef patty component (see Part VI of this directive). Ground or chopped products made from both beef and other meat or poultry products and beef sausage products are not subject to FSIS' *E. coli* O157:H7 sampling and testing.

B. How is raw ground beef product sampling conducted at official establishments?

1. When the Office of Public Health and Science (OPHS) schedules samples to be taken at an establishment, OPHS will send the Inspector-in-Charge (IIC) FSIS Form 10,210-3, "Requested Sample Programs." OPHS will send the form electronically in the near future. Specific information for the sample to be collected will be included on the sample request or in revisions to FSIS Directive 10,210.1, under the appropriate project.

2. Inspection program personnel may be instructed to collect more than one sample per lot in certain circumstances (e.g., if FSIS has reason to believe that product is at high risk of being contaminated with *E. coli* O157:H7 because of illnesses or outbreaks that may have been associated with the establishment, or because the establishment or its suppliers have previously produced product that tested positive in FSIS-collected verification samples for *E. coli* O157:H7).

3. Before collecting samples, inspection program personnel are to notify official establishment management that they will be collecting a sample and are to provide enough time for the establishment to hold the sampled lot. Inspection program personnel are to inform the establishment of the reason they are taking the sample (e.g., routine FSIS verification testing, follow-up sampling in response to an *E. coli* O157:H7 positive, traceback sampling, or follow-up sampling in response to an *E. coli* O157:H7 outbreak).

4. Inspection program personnel collect samples from the current day's production, and the samples should be, whenever possible, in their final packages. Samples should not be sent to the laboratory until the establishment has completed pre-shipment review for that lot. If product from final packages is not available for sampling, inspection program personnel should collect an aseptic sample. Products should be held under security following established Agency controls.

5. If a sample must be held overnight, it must be refrigerated. If a sample must be held longer than overnight, it must be frozen.

6. After the establishment completes the pre-shipment review, inspection program personnel should prepare the sample to be sent to the laboratory on the first available Federal Express pick-up.

Part III – Supplier Information

A. What actions does FSIS take when there is an FSIS presumptive *E. coli* O157:H7 positive for a raw ground beef product sample?

1. Every FSIS verification sample that is eventually confirmed positive by FSIS for *E. coli* O157:H7 goes through three stages of analysis. The results of each stage are reported to IIC's on LEARN. These samples are initially screened and, as appropriate, are reported as "Potential Positives." At the next stage, based on laboratory results, some samples are reported as "Presumptive Positives." Because most "Presumptive Positives" are eventually confirmed, the contact person in the District where the establishment is located needs to immediately inform the establishment that the sample is a "Presumptive Positive." At the same time, the District contact person also informs the establishment management that if the results are confirmed positive, FSIS will collect the following information regarding the suppliers of the source materials used in the production of the product (9 CFR 320.1):

a. name of the supplying establishment, point of contact (name, title, e-mail address, and fax number), and phone number of supplying establishment;

b. supplier lot number; and

c. production date, name of supplied material, and any additional information to clearly identify the material used to the management of the supplying establishment.

2. If the source materials are from a foreign establishment, the District contact person should inform the establishment that FSIS will also collect the following information, should the product be confirmed positive for *E. coli* O157:H7:

a. country of origin;

b. foreign establishment number;

c. shipping mark;

d. I-house; and

e. barcoding or any other information that identifies the origin of the product.

3. The District contact person advises the establishment that it should begin to gather the information above, along with distribution information.

B. What information does FSIS collect when a raw ground beef product sample collected by FSIS for verification testing at an official establishment is confirmed positive for *E. coli* O157:H7, and whom does FSIS notify concerning the positive?

1. When a sample is confirmed positive, inspection program personnel collect from the establishment the information in Part III. A. Inspection program personnel make note of any information that the establishment is unable to provide.

2. Inspection program personnel forward the information by e-mail to the designated DO contact, with a "cc" to the front-line supervisor.

3. The DO will access the System Tracking *E. coli* O157:H7 – Positive Suppliers (STEPS), open a case file for the incident, and follow STEPS procedures.

4. STEPS automatically e-mails the DO that has jurisdiction over the supplying establishment. The DO notifies the IIC at the supplying establishment to perform a HACCP 02 and other activities described in Part VI.

5. The DO notifies all of the supplying establishments in the District, by telephone, of the positive finding and provides the suppliers the production date for the product that the supplier provided to the grinder, the lot number of the supplied product, and other information that would be useful to the supplier to help identify the *E. coli* O157:H7 positive lot. The DO documents the date and time of this oral notification in the STEPS system.

6. After all necessary information on the supplying establishment has been entered into the STEPS system, the DO reviews the information in the STEPS system and sends an e-mail notification to the supplier about the *E. coli* O157:H7 positive product.

7. The supplier information is maintained within the STEPS system and is maintained on FSIS' network. Users must be given access to this site.

NOTE: If the confirmed positive sample came from product which was made, in whole or in part from imported product, the DO provides information about the supplier to the Office of International Affairs (OIA), Import-Export Programs Staff, by telephone, and documents the date and time of this oral notification in the STEPS system. The DO then provides information about the supplier to OIA, Import-Export Programs Staff, through an e-mail message to importexport@fsis.usda.gov. OIA, in turn, forwards this information to the head of the inspection service in the country where the supplying establishment is located.

Part IV – Enforcement Actions in Official Establishments

A. What actions do inspection program personnel take if an FSIS sample taken from an official establishment is confirmed positive for *E. coli* O157:H7?

1. The DO is notified of a positive through the Biological Information Transfer and E-mail System (BITES).
2. Inspection program personnel, the DO, and Recall Management Staff (RMS) work together to determine the necessity of product retention, detention, or recall. The Technical Services Center (TSC) and OPHS may also serve as technical resources to assist in the decision making process. The DO will contact inspection program personnel and program investigators as necessary (see FSIS Directive 8080.1, Revision 3).
3. As set out in FSIS Directive 5000.1, Revision 1, inspection program personnel are to:
 - a. issue an NR under the appropriate 03 ISP code using the “verification” trend indicator; and
 - b. as soon as possible after the establishment has implemented its corrective action, perform a HACCP 02 procedure for the specific production that tested positive for *E. coli* O157:H7 and verify that the establishment implements corrective action that meets the requirements of:
 - i. 9 CFR 417.3(a) if *E. coli* O157:H7 is addressed in the HACCP plan;
 - ii. 9 CFR 417.3(b) if *E. coli* O157:H7 is not addressed in the HACCP plan or if it is addressed in prerequisite programs; or
 - iii. 9 CFR 417.3(b) and 416.15 if *E. coli* O157:H7 is addressed in the Sanitation SOPs.
4. If disposition of the positive product will be delayed, inspection program personnel should work with their front-line supervisors to determine how to work with the establishment to ensure proper and timely disposal of the product.
5. If product disposition is to occur off site, inspection program personnel are to verify that the establishment that produced the positive product maintains appropriate control of the product by conducting the following activities when performing the 02 procedure:

a. obtaining the identity of the official establishment or obtaining the name and address of any renderer or landfill that will receive the product;

b. notifying, through e-mail, the contact person in the District that covers the establishment that produced the positive product that adulterated product is being transferred and providing the DO contact person the establishment number of the establishment where disposition will occur or the name and address of the landfill operation or renderer. The District contact person will notify the District where the establishment that will further process the product, landfill operation, or renderer is located, if the establishment, landfill operation, or renderer that is to receive the product is located in another District;

c. for product being transferred to a landfill operation or renderer, verifying that the establishment will maintain control of the positive product while it is in transit (e.g., through company seals);

d. for product being transferred to an official establishment, verifying that either 1) the establishment that produced positive product will maintain control of the product while it is in transit (e.g., through company seals) or 2) the product will move under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1); and

e. verifying that records are available that show that the positive product received the proper disposition, including documentation evidencing proper disposal of the product from the official establishment, landfill operation, or renderer where disposition occurred. The HACCP 02 procedure at the establishment that produced the positive product cannot be completed for this specific production until the establishment has conducted pre-shipment review of the corrective action record and has received documentation evidencing proper disposal from the official establishment where disposition occurred or landfill operation or renderer where disposition occurred.

6. If inspection program personnel find noncompliance with paragraph 5, they are to contact the DO. The DO will investigate to determine whether the establishment committed the prohibited act of selling or transporting adulterated articles that have not been inspected and passed.

Part V – Follow-up Sampling

A. Are FSIS follow-up samples taken at official establishments after an FSIS-sample of raw ground beef is confirmed positive for *E. coli* O157:H7?

1. If inspection program personnel identify no significant problems through the HACCP 02 procedure (see Part IV. A. 3. b.), inspection program personnel are to contact OPHS through an Outlook e-mail message to **Sampling Forms – Headquarters** mailbox, so a form can be sent for the collection of a follow-up verification sample. Inspection program personnel should copy (CC) their front-line supervisor and the DO designated representative on their e-mail message. The request must include the establishment number, the number of forms (in this case 1), the type of sample to be collected (i.e., a product sample), the purpose of the request

(i.e., follow-up sampling in response to a confirmed positive in raw ground beef), the sample form number of the original positive sample triggering this request, and the DO official approving the request. Instructions for follow-up sampling will be provided on FSIS Form 10,210-3, Requested Sample Programs, or in revisions to FSIS Directive 10,210.1, under the appropriate project. Inspection program personnel should collect the follow-up sample as soon after the establishment has taken its corrective action as possible. See Part V. A. 3., for actions to take if disposition of the positive product is delayed.

2. If inspection program personnel identify regulatory noncompliance, they should document the noncompliance in accordance with FSIS Directive 5000.1, Revision 1, Chapter IV. If inspection program personnel find that the establishment may have moved positive product without appropriate controls or if they find the establishment may not have records showing that positive product received proper disposition, they should contact the DO. Inspection program personnel should also collect one follow-up sample as soon after the establishment has taken its corrective action as possible. Inspection program personnel are to contact OPHS so a form can be sent for the collection of a follow-up verification sample. See Part V. A. 1., for information on e-mailing OPHS to request a follow-up sampling form. See Part V. A. 3., for actions to take if disposition of the positive product is delayed.

3. If disposition of the positive product will be delayed, inspection program personnel should work with their front-line supervisors to determine when it would be appropriate to collect the follow-up sample and how to work with the establishment to ensure proper and timely disposal of the product.

4. If the inspection program personnel have concerns regarding whether the design of the HACCP system is adequate to ensure food safety, they should not collect a follow-up sample. They should notify their front-line supervisor, who will determine whether it is necessary to bring in an Enforcement Investigations and Analysis Officer (EIAO) to the establishment to conduct a comprehensive assessment of the food safety systems. If the EIAO determines that the establishment's corrective actions appear to be appropriate and effective, the EIAO will contact OPHS so a form can be sent to inspection program personnel for the collection of a follow-up verification sample. See Part V. A. 1., for information on e-mailing OPHS to request a follow-up sampling form. Inspection program personnel are to take the sample as soon as possible after they receive the form. See Part V. A. 3., for actions to take if disposition of the positive product is delayed.

5. If a follow-up sample is found positive, the DO is notified through BITES, and the DO will determine the appropriate follow-up action.

6. If the EIAO determines that the corrective actions are inappropriate or ineffective, the EIAO will recommend an enforcement action as described in 9 CFR 500.3 or 500.4 (e.g., Notice of Intended Enforcement (NOIE), withholding, or suspension).

7. If the District Office decides to either defer a decision on suspending the establishment, or a suspension action is taken and then put into abeyance (see FSIS Directive 5000.1, Revision 1, Chapter IV), FSIS will conduct follow-up sampling to verify that the corrective action taken by the establishment is appropriate and effective. The DO will determine the number of follow-up samples to be taken based on guidance that will be available to the DO before the implementation date of this Directive. The DO should contact OPHS so the appropriate number of forms can be sent to inspection program personnel for the collection of follow-up verification samples. See Part V. A. 1., for information on e-mailing OPHS to request follow-up sampling forms. The guidance is designed to provide enhanced statistical confidence for finding low levels of *E. coli* O157:H7 but is not designed to provide validation of the establishment's food safety system.

PART VI - FSIS' Verification Activities at Establishments Producing Raw Ground Beef Components or Raw Beef Patty Components

A. If FSIS confirms raw ground beef product at an official establishment or retail facility positive for *E. coli* O157:H7, and a second official establishment supplied the product used to produce the ground product, what verification activities does FSIS conduct at the supplying establishment?

The IIC at the supplying establishment ensures that the inspection program personnel perform a HACCP 02 procedure to verify that the establishment met the applicable regulatory requirements at all CCPs in the HACCP plan (monitoring, verification, recordkeeping, corrective actions, and reassessment) for the production lots sent to the establishment or retail facility where FSIS found the positive. If inspection program personnel find noncompliance, they take appropriate action as described in FSIS Directive 5000.1, Revision 1, Chapter IV.

B. If a grinding establishment or retail facility receives incoming product for grinding, and FSIS finds the raw ground product positive for *E. coli* O157:H7, will FSIS test product from suppliers? If so, how do inspection program personnel collect samples?

1. When FSIS conducts sampling at official establishments or at retail, and a sample tests positive for *E. coli* O157:H7, FSIS may test raw ground beef components and raw beef patty components at the supplying establishment.

2. If inspection program personnel are requested to collect raw ground beef components or raw beef patty component samples, they are to follow the instruction in Part II of this directive and collect samples as described in Attachment 2. The types of product inspection program personnel may collect are:

Raw Ground Beef Components: These components include raw esophagus (weasand) meat, head meat, and cheek meat; beef manufacturing trimmings (e.g., 90/10, 85/15, 75/25, 65/35, 50/50); boneless beef; beef from AMR systems; and lean finely textured beef (LFTB).

Raw Beef Patty Components: These components include all the components listed above in Raw Ground Beef Components, as well as partially defatted chopped beef (PDCB), finely textured PDCB; heart; and partially defatted beef fatty tissue (PDBFT).

3. Also, inspection program personnel are to only collect samples of raw ground beef components or raw beef patty components that are intended for use in raw non-intact product. To determine the intended use of the products, inspection program personnel are to review establishment records and HACCP documents. In cases where the establishment records and HACCP documents (e.g., flow chart and hazard analysis) are unclear about the intended user, FSIS will handle the product as if it were intended for use in raw non-intact product. If the establishment has not identified the intended use or consumers of the finished product, the establishment is out of compliance with 9 CFR 417.2(a)(2).

C. If FSIS finds raw ground beef product at an official establishment positive for *E. coli* O157:H7, and the ground product was derived from raw ground beef components produced at the same establishment, would FSIS sample raw ground beef components at that establishment?

FSIS may sample and test raw ground beef components at an establishment that produces raw ground beef products from such components if FSIS finds the ground beef product positive. If instructed to sample such products, inspection program personnel should follow the sampling procedures in Part VI. B.

D. What enforcement actions do inspection program personnel take if FSIS finds a raw ground beef component or raw beef patty component positive for *E. coli* O157:H7?

Inspection program personnel are to follow the instructions in Part IV. A. The enforcement actions inspection program personnel are to take when FSIS finds a raw ground beef component or raw beef patty component positive for *E. coli* O157:H7 are the same as the enforcement actions inspection program personnel are to take when FSIS finds a raw ground beef product positive for *E. coli* O157:H7. Similarly, the controls necessary for movement of presumptive positive or positive raw ground beef products are also necessary for movement of presumptive positive or positive raw ground beef components or raw beef patty components.

PART VII – Inspection program personnel responsibilities related to an establishment's testing of product for *E. coli* O157:H7

A. Can establishments conduct pre-shipment review for product that is not at the producing establishment?

FSIS has taken a consistent position that establishments can conduct pre-shipment review when the product is at locations other than at the producing establishment provided that the product does not leave the control of the producing establishment. Some establishments analyze samples for *E. coli* O157:H7 while the product is being moved but is still under the establishment's control. FSIS is providing the establishments the flexibility to move this product prior to pre-shipment review being conducted when the establishment is conducting testing for *E. coli* O157:H7 and maintains control of the product. FSIS has instructed inspection program personnel that they have access to the results of any testing and of any monitoring activities that are performed that may have an impact on the establishment's hazard analysis (FSIS Directive 5000.2). Inspection program personnel must review these results on at least a weekly basis.

B. What do inspection program personnel verify if an establishment conducts verification testing for *E. coli* O157:H7?

1. Inspection program personnel are to review the records associated with any *E. coli* O157:H7 testing conducted by an establishment. If inspection program personnel find a presumptive positive or confirmed positive *E. coli* O157:H7 result in the testing records, they should verify that the establishment is implementing corrective actions that meet the regulatory requirements as part of a HACCP 02 procedure as described in Part IV.

2. If establishment records show that the establishment transports product that it has found presumptive positive or positive for *E. coli* O157:H7 to another establishment for appropriate disposition, or if establishment records show that the establishment moves product before *E. coli* O157:H7 test results become available, inspection program personnel should verify that the establishment—

a. maintains records identifying the official establishment, renderer, or landfill operation that received presumptive positive or positive product;

b. maintains records identifying the official establishment that is to receive product for which results are pending;

c. maintains control of product that is destined for a landfill operation or renderer while the product is in transit (e.g., through company seals);

d. maintains control of product that is destined for an official establishment while the product is in transit (e.g., through company seals) or ensures such product moved under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1);

e. maintains records that show that presumptive positive or positive product, including product that moved pending test results, received the proper disposition, including documentation evidencing proper disposal of the product from the official establishment, renderer, or landfill where disposition occurred; and

f. completes pre-shipment review for product from a lot that has tested positive or presumptive positive and that was moved pending test results only after it has the records described in paragraph e. for that particular product.

3. If inspection program personnel are aware that an establishment has found product presumptive positive or positive for *E. coli* O157:H7, and that the establishment is currently moving the product for further processing to destroy the pathogen or for destruction, they should verify that the establishment moves the product using the appropriate controls identified in Part VII. B. 2. Inspection program personnel should also notify the DO where the establishment that produced positive or presumptive positive product is located, through e-mail, of the establishment number or name and address of the renderer or landfill operation that is to receive the product. The DO contact person will notify the contact person in the District where the establishment, landfill operation, or renderer that is to receive the product is located, if that establishment, landfill operation, or renderer is located in another District.

4. If inspection program personnel find noncompliance with Part VII. B., 1., 2., or 3., they should contact the DO. The DO will investigate to determine whether the establishment committed the prohibited act of selling or transporting adulterated articles that have not been inspected and passed.

5. The HACCP 02 procedure for a specific production at the establishment that produced the positive or presumptive positive product cannot be completed until that establishment completes pre-shipment review, including review of the corrective action record, and has received documentation evidencing that product has been properly disposed of from the official establishment where disposition occurred or renderer or landfill operation where disposition occurred.

NOTE: When an establishment tests product, a presumptive positive or positive result alone does not warrant an NR. Inspection program personnel are only to issue an NR in response to an establishment's presumptive positive or positive finding if the establishment fails to take the appropriate actions to meet the requirements in 9 CFR 417.3.

PART VIII – Receiving raw ground beef products, raw ground beef components, and raw beef patty components that are positive for *E. coli* O157:H7

What should inspection program personnel do at an establishment that receives raw ground beef products, raw ground beef components, and raw beef patty components that FSIS or an establishment has found positive for *E. coli* O157:H7?

When inspection program personnel perform a HACCP 01 or 02 procedure at an establishment that has received product from a lot that was found positive for *E. coli* O157:H7 product, they are to verify that:

1. the establishment documents the receipt of presumptive positive or positive product, as required under 9 CFR 417.5;
2. the establishment maintains control of the product; and
3. *E. coli* O157:H7 is addressed in the establishment's hazard analysis and HACCP plan, so that the positive product will receive an adequate lethality treatment to destroy the pathogen.

If inspection program personnel find noncompliance, they take appropriate action as described in FSIS Directive 5000.1, Revision 1, Chapter IV.

Part IX -- Verification Procedures Involving Instructional or Disclaimer Statements Concerning *E. coli* O157:H7

A. What is an instructional or disclaimer statement concerning *E. coli* O157:H7?

1. An instructional statement concerning *E. coli* O157:H7 is a statement that addresses how the product should be prepared or handled to ensure that the pathogen is eliminated or reduced to an undetectable level. Examples of instructional statements concerning *E. coli* O157:H7 in raw ground beef components, raw beef patty components, and raw ground beef products may include, "for full lethality treatment" or "for cooking only." "Cooking" is applying heat to a product at a sufficient temperature and for a sufficient period of time to eliminate *E. coli* O157:H7 or reduce the pathogen to an undetectable level, and "full lethality treatment" may be cooking or another process that eliminates *E. coli* O157:H7 or reduces the pathogen to an undetectable level, such as fermentation or salt curing.

2. A disclaimer statement concerning *E. coli* O157:H7 is a statement regarding the type of verification activities addressing the pathogen that were NOT used in the production of the product. An example of a disclaimer statement concerning *E. coli* O157:H7 is, "product has not been tested for *E. coli* O157:H7."

B. What type of products can bear these labeling statements?

Establishments can only place these statements on product for use at other official establishments. When the Labeling and Consumer Protection Staff (LCPS) approves the use of instructional labeling statements, LCPS specifies that such statements can only be used on products destined for official establishments that ensure these products receive adequate lethality treatment. When LCPS approves the use of disclaimer labeling statements, LCPS specifies that such statements can only be used on products destined for official establishments that address *E. coli* O157:H7 in their HACCP plan. Establishments' use of these statements is entirely optional.

C. What verification activities should inspection program personnel conduct at establishments that place instructional or disclaimer statements concerning *E. coli* O157:H7 on the labeling of raw ground beef products, raw ground beef components, or raw beef patty components?

1. When conducting an 04B04 procedure, inspection program personnel are to verify that the establishment has received sketch approval from LCPS and that it is maintained in the company's required labeling records (see 9 CFR 317.4(a)).

2. If inspection program personnel find that the establishment did not receive sketch approval or does not maintain that sketch approval in its official labeling records, they are to document the noncompliance on an NR under the Inspection System Procedure (ISP) code 04B04, and they are to document noncompliance with 9 CFR 317.4(a).

3. When performing a HACCP 01 or 02 procedure to verify the HACCP regulatory requirements are met for the production of such products, inspection program personnel are to verify that:

a. the instructional or disclaimer statement does not serve as a control or CCP to address *E. coli* O157:H7;

b. the establishment has not used the statement to justify its determination that *E. coli* O157:H7 is NOT a hazard reasonably likely to occur in the production of these products;

c. the use of any instructional statements is reflected in the establishment's decisionmaking documents (9 CFR 417.5) or hazard analysis (9 CFR 417.2(a)(1)); and

d. the establishment's HACCP plan for products on which it places a disclaimer statement includes a validated intervention for *E. coli* O157:H7.

4. If inspection program personnel find that the establishment's use of instructional statements does not meet the criteria in paragraph 3. a., b., or c. or that the establishment's use of disclaimer statements does not meet the criteria in paragraph 3. a. or b., they are to document the noncompliance on an NR as described in FSIS Directive 5000.1, Revision 1, Chapter IV using the 03-01 or 03-02 ISP code and the appropriate regulatory citation.

5. If inspection program personnel find that the establishment's HACCP plan for product on which it places a disclaimer statement does not include an intervention for *E. coli* O157:H7, they are to document the noncompliance on an NR as described in FSIS Directive 5000.1, Revision 1, Chapter IV, using the 03-01 or 03-02 ISP code and the appropriate regulatory citation. If inspection program personnel are concerned about product moving outside the establishment, they should initiate a regulatory control action (9 CFR 500.2).

D. What verification activities should inspection program personnel conduct at establishments receiving raw ground beef components, raw beef patty components, or raw ground beef products with instructional or disclaimer statements concerning *E. coli* O157:H7?

1. When performing an 01 or 02 procedure to verify the HACCP requirements are met for products produced using such incoming products, inspection program personnel are to verify that establishments that receive such incoming products:

a. have addressed the use of incoming product with disclaimer statements in their HACCP plan as if the product may be contaminated with *E. coli* O157:H7; and

b. are following any instructional statements on the incoming products.

2. If inspection program personnel find that the establishment has not met the criteria in paragraph 1., they are to document the noncompliance on an NR as described in FSIS Directive 5000.1, Revision 1, Chapter IV using the 03-01 or 03-02 ISP code and the appropriate regulatory citation.

3. Inspection program personnel should retain product produced using such incoming products under the following conditions:

a. the establishment is not following the instructional statement, or the establishment is receiving product bearing a disclaimer statement and its hazard analysis or decisionmaking documents do not address the use of the incoming product as if it were contaminated with *E. coli* O157:H7;

b. the establishment's process may not be adequate to eliminate or reduce *E. coli* O157:H7 to undetectable levels; and

c. the product is not intended for further processing that would destroy the pathogen.

4. If inspection program personnel retain product, they are to document the noncompliance on an NR as described in FSIS Directive 5000.1, Revision 1, Chapter IV using the 03-01 or 03-02 ISP code and the appropriate regulatory citation. Inspection program personnel should also notify the DO through supervisory channels of the conditions observed in association with the use of instructional or disclaimer statements. The DO may send an EIAO into the establishment to conduct a comprehensive food safety assessment or invoke an enforcement action as described in 9 CFR 500.3 or 500.4.

PART X -- Retail Sampling

A. How is raw ground beef product sampling conducted at retail?

1. Retail sampling continues to be an important part of FSIS' *E. coli* O157:H7 sampling program. The likelihood that a specific retail facility will be sampled will depend on what the Agency learns about how raw ground beef product is handled at that facility.

2. When OPHS schedules samples to be taken at retail facilities, OPHS will send OPEER offices FSIS Form 10,210-3, "Requested Sample Programs." Specific information will be provided for the samples to be collected.

3. Program investigators are to make an effort to notify the retail facility the day before they plan to collect the raw ground beef product samples, so that the retail facility can prepare to hold the expected sampled lot. However, in cases when this is not possible, program investigators should try to get to the retail facility as close to the beginning of the grinding operation as possible.

4. Program investigators do not collect raw ground beef product that is received and sold as case-ready product or raw ground beef product that is only re-packaged at the retail store. Program investigators also do not collect raw ground beef product that is ground at retail if the retail facility only regrinds product previously ground at official establishments and does not conduct any practices that would introduce *E. coli* O157:H7 in the product (examples of situations in which samples should be taken include when the store mixes irradiated and un-irradiated beef; adds store trim; or grinds case-ready coarse ground product in a grinder also used to grind store trim if the sanitation program is not well documented, monitored, and verified for effectiveness).

5. When they collect the sample, program investigators obtain from the retail facility the names and establishment numbers of the establishments supplying the source materials for the lot of raw ground beef product sampled.

NOTE: When the source material for the sampled product is store-generated trim, the program investigator obtains and records the names and establishment numbers of the establishments that produced the product from which the store-generated trim was derived.

6. The supplier information is recorded on the retail worksheet that is used specifically for collection of raw ground beef products at retail.

7. In addition, the program investigator records the supplier lot number, production date, and other identifying information that would be useful to the supplier if it is later notified of a positive sample.

B. If a sample of raw ground beef product from a retail facility is confirmed positive for *E. coli* O157:H7, what actions does FSIS take to ensure that adulterated product is kept out of commerce?

The retail facility is notified of the positive *E. coli* O157:H7 result by the program investigator. FSIS will request a recall if any product in the sampled lot has been made available for retail sale. Program investigators and RMS are to work together to determine the necessity of product retention, detention, or recall. (See FSIS Directive 8080.1, Revision 3).

C. Whom does FSIS notify when a raw ground beef product sample at a retail facility is confirmed positive for *E. coli* O157:H7, and how is the notification given?

1. OPEER is notified of a retail positive through the Biological Information Transfer and E-mail System (BITES) and enters supplier information into the STEPS system.

2. The OPEER contact person accesses the STEPS system site with the list of suppliers for the sampled product that tested positive and follows the procedures for notifying suppliers in Part III. B.

D. If FSIS finds raw ground beef product produced at retail positive for *E. coli* O157:H7, does FSIS conduct follow-up sampling at the retail facility?

After an FSIS sample tests positive, program investigators should contact OPHS through an Outlook e-mail message to **Sampling Forms – Headquarters** mailbox, so a form can be sent for the collection of a follow-up sample. The request must include the retail facility name and address, the number of forms (in this case, 1), the type of sample to be collected (i.e., product sample), the purpose of the request (i.e., follow-up sampling in response to a confirmed *E. coli* O157:H7 positive in raw ground beef), the sample form number of the original positive sample triggering this request, the date by which the form is needed, and the program investigator's name and work address. Instructions for follow-up sampling will be provided on FSIS Form 10,210-3, "Requested Sample Programs" or in revisions to FSIS Directive 10,210.1, under the appropriate project. In addition, when feasible, FSIS will schedule

verification activities, including testing, at the supplying establishment following an FSIS positive sample from a retail facility.

PART XI -- Import Sampling

A. How is raw ground beef product sampling conducted at import establishments?

1. OPHS works with the Office of International Affairs (OIA) to send import inspection personnel FSIS Form 10,210-3, "Requested Sample Programs." Certain information will be provided specific to the sample to be collected. Import inspection personnel are to follow the corresponding instructions found in the Import Manual of Procedures (Part 3, Section 5). When OPHS begins sending the form electronically, the Automated Import Information System (AIIS) will schedule samples and send the form electronically to import inspection personnel.

2. Import inspection personnel notify the import establishment management of the reason a sample is being collected for *E. coli* O157:H7 testing (routine FSIS verification testing, increased sampling, or intensified sampling). Imported products may be under increased sampling if OIA has determined that product may be at risk of being contaminated with *E. coli* O157:H7. When a shipment is to be sampled for FSIS testing, the importer, broker or applicant has an opportunity to voluntarily hold the product until the results are reported. Positive samples from imported products result in an intensified level of sampling of subsequent shipments from the foreign establishment. When a foreign establishment is under intensified sampling for *E. coli* O157:H7, FSIS holds the product to be sampled until negative results are reported by the laboratory.

B. If a sample of imported raw ground beef product collected from an import establishment is confirmed positive for *E. coli* O157:H7, what actions does FSIS take to ensure that adulterated product is kept out of commerce?

1. If the product is on hold at the import establishment, whether on FSIS hold or voluntary hold, import inspection personnel will initiate refused entry procedures on the entire lot.

2. FSIS will request a recall if any product in the sampled lot has been released into commerce. Program personnel, including OIA, the DO, and RMS, work together to determine the necessity of product retention, detention, or recall. OIA will coordinate with the DO to provide information to inspection program personnel and program investigators as necessary.

C. Whom does FSIS notify when an imported raw ground beef product collected at an import establishment is confirmed positive for *E. coli* O157:H7, and how is notification given?

1. If the lot has not moved into commerce, import inspection personnel notify establishment management, which is responsible for notifying the importer of record. Import inspection personnel should refer to Part 4, Section 11 of the Import Manual of Procedures for guidance on refused entry procedures.

2. If the lot has moved into commerce from the import establishment:

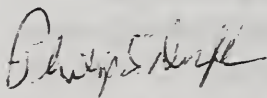
a. the import inspection personnel should send a copy of FSIS Form 9540-1 and the foreign health certificate via facsimile to OIA/Import Inspection Division.

b. OIA notifies the head of the inspection service in the country of origin of the sample that has been confirmed positive for *E. coli* O157:H7 and requests that appropriate action be taken.

D. If FSIS finds raw ground beef product collected at an import inspection establishment positive for *E. coli* O157:H7, does FSIS conduct follow-up sampling of product from the foreign establishment?

Positive samples from imported products result in an intensified level of sampling of subsequent shipments from the foreign establishment. An intensified level of sampling is automatically generated by the AIIIS for the next 15 consecutive shipments of product from the foreign establishment presented at port-of-entry anywhere in the United States. Under an intensified level of sampling, the shipment is placed on FSIS hold when the sample is collected, until results are reported. Import inspection personnel should follow the procedures outlined in the Import Manual of Procedures (Part 3, Section 5) for guidance.

All questions related to this directive should be directed through normal supervisory channels.



Assistant Administrator
Office of Policy and Program Development

Attachment 1

Questions and Answers

1. Will FSIS sample trimmings and other ground beef and beef patty components?

FSIS may sample and test beef manufacturing trimmings and other raw ground beef and beef patty components at a supplying establishment when that establishment has supplied product to grinders that tested positive for *E. coli* O157:H7 after it was ground. In the future, FSIS intends to develop a random sampling and testing program for raw ground beef components and beef patty components and non-intact beef products other than ground beef, such as mechanically tenderized and injected steaks and roasts.

2. Will an establishment that has incorporated testing of trimmings and ground beef products for *E. coli* O157:H7 into its HACCP plan as a verification procedure be exempt from FSIS sampling and testing?

No establishment that produces raw ground beef products, raw ground beef components, or raw beef patty components will be exempt from FSIS sampling and testing for *E. coli* O157:H7. However, FSIS' verification testing will become more risk-based. Establishments that have designed and implemented sampling and verification testing, with a high degree of confidence of finding the pathogen in both trim and finished ground product, presumably present a lower risk for producing adulterated product than one that conducts this activity only on trim or only on finished ground product and, therefore, will be sampled less frequently than other establishments.

3. What factors will be considered by FSIS in establishing risk-based verification testing for *E. coli* O157:H7 in federally-inspected establishments?

FSIS will weight its sample scheduling process so that an establishment producing a large volume of raw ground beef products will be sampled more frequently than an establishment with a lower volume of production of raw ground beef products. In addition, FSIS will also consider seasonality of *E. coli* O157:H7 prevalence and other factors, such as the number of suppliers, in developing a sampling plan based on risk. FSIS will also sample ground beef product at inspected establishments that form ground beef patties but do not grind the product. However, FSIS will also sample ground beef product at these establishments less frequently than at a plant that grinds product.

4. What factors are considered by FSIS in ensuring that retail sampling focuses on the highest risk product?

Retail sampling focuses on higher risk products by focusing on product that either includes store-generated trim or was ground using equipment that had been used to grind store-generated trim without being adequately cleaned.

5. Can an establishment have a CCP for product disposition based on finished product testing?

If a grinder has internal controls for *E. coli* O157:H7 and receives product from suppliers (both slaughter and fabrication establishments) that have controls for *E. coli* O157:H7, and the grinder and its suppliers conduct rigorous verification testing at multiple points during the production process, a CCP for disposition based on finished product testing for *E. coli* O157:H7 may be appropriate. A CCP for disposition based on finished product *E. coli* O157:H7 testing should employ testing at a level sufficient to find the organism if present at very low frequency. Corrective and preventive action in response to a positive in finished product testing should accompany an examination of the whole system, not merely disposition of the product.

6. Can the FSIS guidance materials suffice for supporting documentation for validation of CCPs, or does FSIS expect the scientific supporting documents to be more specific than a copy of the FSIS guidance materials?

The guidance materials that FSIS has developed for slaughter establishments, grinders, and suppliers on minimizing the risk of *E. coli* O157:H7 contamination included the parameters of certain studies. If establishments can demonstrate that their process meets the parameters of those studies, the FSIS guidance materials would be sufficient documentation of their validation. However, if the process parameters in the establishment differ from those in the FSIS guidance materials, in-house validation would be necessary.

7. If the establishment or FSIS tests raw ground beef products, raw ground beef components, or raw beef patty components for *E. coli* O157:H7 and finds more than one positive, do these findings signify a HACCP failure?

The establishments' or FSIS' finding more than one positive would not alone be a HACCP failure. However, FSIS would expect the establishment to identify *E. coli* O157:H7 as a hazard reasonably likely to occur (if it has not already done so). In addition, the establishment should attempt to determine the cause of the positive findings and would likely need to examine its intervention methods to determine why they are not working. Some establishments have adopted intensive raw material and finished product testing and supplier controls within their Sanitation SOPs and HACCP systems. In these situations, inspection program personnel should verify that the establishments control procedures to determine whether a HACCP failure is occurring. In other situations, the establishment may decide to conduct carcass mapping to identify areas of carcass contamination (if the establishment conducts slaughter or fabrication). In addition, if FSIS testing finds *E. coli* O157:H7, the establishment may

decide to intensify its verification program or may decide to ensure that the sensitivity of its testing method is equivalent to FSIS' testing method.

8. Can an inspector collect and submit a ground beef sample prior to pre-shipment review being performed by the establishment?

Inspection program personnel should become familiar with the production process and provide notification to the establishment that a sample will be collected in time for the establishment to hold the sampled product. Some establishments have an extensive verification testing program, sample every "lot" of ground beef product produced, and have a CCP for product disposition. In this scenario, the establishment cannot conduct pre-shipment review until the result from the sample has been received. If the establishment has no interventions in place after the product is sampled that address the presence of the pathogen of concern, the establishment could conduct a pre-shipment review on this product up to this point with a note indicating that the product is being held pending laboratory analysis. Inspection program personnel could verify that the establishment meets the corrective action requirements of 9 CFR 417.3, if a positive result is received by the establishment. If disposition of product is delayed, inspection program personnel should work with their front-line supervisors to determine how to work with the establishment to ensure proper and timely disposal of the product. When the results for both samples (FSIS sample and the establishment sample) have been received, the establishment could then conduct a "final" pre-shipment review. In a scenario similar to this, inspection program personnel could submit the sample prior to the final pre-shipment review being conducted.

9. If an establishment makes case-ready product and requests that the inspector give it notice the day before the inspector is to take a sample, so that the establishment can adjust its production levels to fill its orders but still hold the sampled lot, should the inspector accommodate the request?

Yes. The purpose of FSIS sampling is to provide verification that the establishment's process is producing product that is not adulterated by *E. coli* O157:H7. It is not to compromise the establishment's ability to fill its orders.

10. What is the purpose of follow-up sampling by FSIS after FSIS finds that a sample of product is positive for *E. coli* O157:H7?

FSIS generally always will collect at least one supplemental verification sample of product immediately following corrective actions by the establishment when FSIS finds a sample of product from an official establishment positive for *E. coli* O157:H7. This follow-up verification sample is expected to be larger (e.g., double the size of the regular verification sample), and FSIS expects to double the number of sub-samples that it analyzes. The results will be reported as either positive or negative, like other

routine verification sample results. FSIS' follow-up sampling is one of several activities FSIS conducts to verify the adequacy of the establishments' corrective actions following an FSIS positive *E. coli* O157:H7 finding.

11. Is FSIS notified of *E. coli* O157:H7 positive Agriculture Marketing Service (AMS) results? If so, what actions do inspection program personnel take in response to such notification?

Yes, FSIS is notified of *E. coli* O157:H7 positive AMS results. AMS reports potential positives and confirmed positives to FSIS. When the DO is notified of an AMS potential positive, FSIS reacts as if the product were found presumptive positive by FSIS (see Part III, A.). If the product is confirmed positive by AMS, the establishment needs to ensure its proper disposition and to conduct appropriate corrective actions. An AMS result is an official government result.

12. Why must establishments obtain sketch approval from FSIS to use labeling that includes instructional or disclaimer statements on raw ground beef products, raw ground beef components, or raw beef patty components?

The labeling of ground beef products, single-ingredient raw ground beef components, or single-ingredient raw beef patty components that includes special instructions or disclaimer statements concerning *E. coli* O157:H7 cannot be generically approved because FSIS considers these special instructions or disclaimers to be special claims (see 9 CFR 317.5(b)(2)).

13. If FSIS finds that establishments have been using labeling that includes instructional or disclaimer statements on raw ground beef products, raw ground beef components, or raw beef patty components without sketch approval from FSIS, will FSIS request that the establishments recall the product?

No. FSIS will not request that establishments recall product that has already been shipped with unapproved labels because use of such product will not result in adverse health consequences. However, FSIS will rescind such labels, and the establishment would need to submit them to FSIS for sketch approval.

14. Can instructional or disclaimer statements serve as controls or CCPs to address *E. coli* O157:H7?

Labeling is not a means to prevent, eliminate, or reduce pathogens. Therefore, instructional or disclaimer statements cannot be used as CCPs or interventions for *E. coli* O157:H7. If the establishment has determined that *E. coli* O157:H7 is a hazard reasonably likely to occur in its production of raw ground beef products, raw ground beef components, or raw beef patty components, the establishment must have an intervention to address the hazard.

15. Can establishments use instructional or disclaimer labeling statements to justify a determination that *E. coli* O157:H7 is not a hazard reasonably likely to occur in their production of beef products?

No. Because labeling is not a means to control pathogens, establishments may not use these labels to justify their determination that *E. coli* O157:H7 is NOT a hazard reasonably likely to occur in their production of these products.

16. Can product labeled “for cooking only” go to an establishment that cooks product intended for additional further processing?

Yes. Even if the product will undergo further processing after it leaves the cooking establishment, as long as the cooking establishment cooks the product at a sufficient temperature and for a sufficient period of time to eliminate or reduce *E. coli* O157:H7 to an undetectable level, the cooking establishment would be complying with the labeling instructions.

17. How should the placement of instructional statements be reflected in HACCP plan documents?

The placement of any instructional statement addressing *E. coli* O157:H7 on labels of raw ground beef products, raw ground beef components, or raw beef patty components must be reflected in an establishment’s decisionmaking documents and hazard analysis.

For example, if an establishment is placing the statement “for cooking only” or “for full lethality treatment” on raw ground beef products, raw ground beef components, or raw beef patty components, the establishment’s hazard analysis should show how the establishment is ensuring that the product will go for cooking only or for other full lethality treatment only. If the establishment places a “for cooking only” statement on the product and cooks the product in the establishment, the establishment’s flow chart should show the cooking steps the product will undergo. If the establishment places a “for cooking only” statement on the product and ships it to outside establishments, the shipping establishment should have controls in place to ensure that the product goes only to establishments that cook it. If the shipping establishment also produces product that is not intended for cooking, it should have controls in place to segregate product intended for cooking from product not intended for cooking. If an establishment places the statement “for cooking only” on its finished product, but the establishment has not addressed the intended use of its finished product in its decisionmaking documents or hazard analysis, the establishment’s hazard analysis and decisionmaking documents would not be consistent with the information contained in the instructional statement, and the establishment would not be in compliance with 9 CFR 417.5.

18. Why are establishments that place labels on raw beef products that include a disclaimer statement concerning *E. coli* O157:H7 required to have an intervention for the pathogen in their HACCP plan?

An establishment may use a disclaimer statement, such as, “not tested for *E. coli* O157:H7,” on labels of raw ground beef products, raw ground beef components, or raw beef patty components only if it has an intervention for the pathogen in its HACCP plan for these products. A disclaimer that the product has not been tested for *E. coli* O157:H7 implies that *E. coli* O157:H7 may be a food safety hazard reasonably likely to occur in the product in the absence of controls. Therefore, the information contained in the disclaimer statement would be inconsistent with a determination in the hazard analysis that it is unnecessary to address this hazard in the HACCP plan, and the HACCP plan may be determined inadequate (9 CFR 417.6).

19. How are inspection personnel to document noncompliances involving labeling and disclaimer statements?

Inspection program personnel are usually to cite 9 CFR 417.5 and to use the recordkeeping trend indicator when documenting on an NR most of the possible noncompliances involving labeling and disclaimer statements. Under 9 CFR 417.5, required records documenting the establishment’s HACCP plan include: a written hazard analysis, supporting documentation of the hazard analysis, a written HACCP plan, and decisionmaking documents associated with selection and development of CCPs and critical limits.

a. If the establishment’s use of instructional statements concerning *E. coli* O157:H7 is not reflected in its decisionmaking documents or hazard analysis, the establishment is not in compliance with 9 CFR 417.5, because its records do not show that the establishment has considered its use of these instructional statements in its hazard analysis or HACCP plan.

b. If the instructional or disclaimer statements serve as controls or CCPs to address *E. coli* O157:H7, the establishment is not in compliance with 9 CFR 417.5 because the establishment’s decisionmaking documents or hazard analysis cannot support its use of instructional or disclaimer statements as controls or CCPs.

c. If the establishment has used instructional or disclaimer statements to justify its determination that *E. coli* O157:H7 is NOT a hazard reasonably likely to occur, the establishment is not in compliance with 9 CFR 417.5 because the establishment’s decisionmaking documents or hazard analysis incorrectly concluded that labeling statements would prevent *E. coli* O157:H7 from becoming a hazard reasonably likely to occur in the establishment.

d. If an establishment receiving product with instructional or disclaimer statements has not addressed the use of such products in its decisionmaking documents or hazard analysis, or does not have data to validate that these products will receive adequate lethality treatment, the establishment is not in compliance with 9 CFR 417.5 because its records do not show that the establishment has adequately addressed the use of these

incoming products in the hazard analysis for those products in which such incoming products will be used.

PROCEDURES FOR SAMPLING RAW GROUND BEEF COMPONENTS AND RAW BEEF PATTY COMPONENTS:

Refer to the page in FSIS Directive 10,210.1 that corresponds to the project code in Block 14 of FSIS Form 10,210-3, Requested Sample Programs, for further collection instructions.

Sample Size:

The FSIS laboratory requires approximately 1.5 pounds (24 ounces or 680 grams) but no less than 1.25 pounds (20 ounces or 570 grams) of product.

Sample Chilling:

If the sample is warmer than 40°F/4.4°C when the sample is taken, place it in a cooler to chill it before shipping.

Prior to shipping the sample, pre-chill the shipping container in a refrigerated cooler that is between 28°F and 45°F for at least 8 hours.

Randomized or Representative Sampling:

As best as practical, select a representative sample by one of the two following procedures:

1. **Time:** Throughout the production lot, as defined by the establishment, as boxes or combo bins are filled, collect samples at random times. Use standard procedures for identifying “random times”.

If random times are not practical use the “Space” option below.

2. **Space:** At or toward the end of the production lot, as defined by the establishment, note the number of boxes or combo bins containing the requested product types. Take the square root of that number and round up to the next whole number (i.e., if the number of boxes is 29, the square root is 5.38; the next whole number is 6). That number, or no more than 10, is the number of containers to be sampled.

Use a standard random number procedure to select which containers to sample. Select representative samples from the top of the filled boxes or combo bins. These pieces should have collected representative bacteria from the product contact surfaces during the course of production.

Sampling Procedure:

There will be three basic sampling procedures based on size of sample pieces:

1. Very small pieces less than the size of an ordinary thumb, such as AMR, or LBT/LFTB.
For very small pieces, use the laboratory-supplied scoop or spoon to collect the sample.
2. Small pieces less than the size of an ordinary palm, such as head meat or trimming.
For small pieces, use the laboratory-supplied scoop, tongs, or hook to collect the sample.

3. Chunks and pieces larger than an ordinary palm, such as chucks and plates:
Call for help from an establishment employee with an establishment knife and laboratory-supplied hook. Have the employee sanitize knife and hook in the same manner as is done on the boning/trim line. From each of the designated containers (or during the day) "Grab sample" pieces with the hook. From each piece, slice a thumb to palm-sized piece of surface, no thicker than ½ inch (or 1 cm). Place the samples into the sterile sample bag, using the hook or laboratory-supplied tongs.

United States Department of Agriculture
Food Safety and Inspection Service
Printing Management Section
5601 Sunnyside Avenue, Mail Drop 5241
Beltsville, MD 20705-5241

FIRST-CLASS MAIL
POSTAGE & FEES PAID
USDA-FSIS
Permit No. G-42

OFFICIAL BUSINESS
Penalty for Private Use, \$300

2751975
- 0538
1992

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

10,200.1

7/19/01

Accessing Laboratory Sample Information via LEARN

I. PURPOSE

What is the purpose of this directive?

The purpose of this directive is to instruct FSIS personnel in how to use the Laboratory Electronic Application for Results Notification (LEARN) system to obtain information about samples submitted to FSIS laboratories for analysis and what to do with the information.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

9 CFR Chapter III

V. TERMINOLOGY

A. What terms are used in this directive?

1. Intranet – An internal web site accessible only by the organization's employees or others with authorization. The **internet** can be used by anyone; an **intranet** can be used only by those who have permission to use it.
2. Potential positive – When the initial screen test is positive during the analysis for *E. coli* O157:H7. Further testing is required to confirm the presence or absence of *E. coli* O157:H7.
3. Presumptive positive – When the initial analytical steps of a microbiological analysis indicate the strong possibility that the organism or toxin in question is present. Additional analytical steps are needed to confirm the presence or absence of the organism or toxin.

DISTRIBUTION: Inspection Offices; T/A Inspectors; OPI: OPPDE
Plant Mgt; T/A Plant Mgt; TRA; ABB; PRD; Import
Offices; Field Service Laboratories

4. Positive, not violative – In residue testing, when the analyte is present, but at or below the tolerance level set by the Food and Drug Administration (FDA) or Environmental Protection Agency (EPA).
5. Violative – In residue testing, when the analyte is present, above the tolerance level set by the FDA or EPA.
6. Acceptable – When the results of all analyses performed on a sample are negative or satisfactory.
7. Not Acceptable - When the results of one or more analyses performed on a sample are positive or not satisfactory.
8. Set Pass – When the *Salmonella* sample set has less than or equal to the maximum number of positives allowed to achieve the performance standard.
9. Set Fail - When the *Salmonella* sample set has more than the maximum number of positives allowed to achieve the performance standard.
10. Indeterminate – Sample results cannot be determined from available data.
11. Non-regulatory – Analysis results are for information only; no regulatory action will be taken based on these results.

VI. BACKGROUND

What is LEARN?

LEARN is a computer application that transmits laboratory results such as microbiological, food chemistry, and residue analyses performed at FSIS laboratories. This system will have the capability to make laboratory sample information available to FSIS program personnel, establishments, and State officials. LEARN will replace the multiple applications currently reporting results through the HPDesk system.

VII. SAMPLE INFORMATION

A. Who will have access to the sample information?

All FSIS personnel with a FSIS Exchange server login will have access to the LEARN intranet page. Within this page, a user may be limited to what sample information he or she may access, such as to information only within a circuit or district.

B. For which types of samples will there be information available on LEARN?

LEARN will provide sample information about pathogens, species identification, food chemistry, and residue testing. The information will cover domestic, import, and State samples.

C. For which types of samples will there be no information available on LEARN?

Enforcement or investigative sample information will not be available at this time. Additional types of information may be added as dictated by the specific program areas.

D. What type of sample information will be transmitted via LEARN?

1. Notification that a sample has been received at an FSIS laboratory, and that the sample is either analyzable or has been discarded.
2. Notification that a sample result will be delayed and an expected completion date.
3. Potential positive or presumptive positive results (for microbial pathogens).
4. Final results.
5. Other sample information may be added as enhancements to LEARN. This information will be defined on help screens available on the LEARN intranet page.

E. How soon will the sample information be available via LEARN?

1. The LEARN application will periodically check the laboratory databases for new sample information to be uploaded on the LEARN Intranet page. Sample information is entered into the FSIS laboratories' databases throughout each day. Users should take into consideration the location of the laboratory to which a sample has been sent. For example, the Western Lab will be posting data about 3 hours later than the Eastern Lab.
2. Once a sample has been shipped to an FSIS laboratory for analysis, the IIC should check LEARN the following afternoon for sample receipt confirmation, and at least once daily until final results are posted. Timely retrieval of, and action on, sample information is important.

F. How long will the sample information be available on LEARN?

Sample information will be posted on the LEARN Intranet page for at least two weeks.

G. How will final results be reported?

1. Pathogens (ready-to-eat (RTE) meat and poultry product samples, raw beef product samples for *E. coli* O157:H7, pasteurized egg product samples) - Acceptable or Not Acceptable
2. *Salmonella* PR/HACCP compliance completed sets – Set Pass or Set Fail
3. Species Identification - Acceptable or Not Acceptable
4. Food Chemistry - Acceptable or Not Acceptable
5. Residue - Not Detected, Positive, Not Violative and Violative
6. Any reported sample – Indeterminate or Non-regulatory

NOTE: For samples submitted for multiple analyses, any positive or otherwise violative analysis result will be reported as soon as determined. Otherwise, if all analyses are negative or non-violative the results will be reported when all analyses are completed.

VIII. LEARN APPLICATION

A. How will FSIS personnel access the LEARN application?

1. Employees must first log on to the USDAFSIS domain through the initial log-on screen when their computer is first turned on. Only after a valid user ID and password have been supplied will an employee be able to access the FSIS Intranet. For employees accessing the USDAFSIS domain via a modem, the normal connection procedures required to access the Agency's e-mail system are sufficient to gain access to the FSIS Intranet.
2. To access sample information, open the Microsoft Internet Explorer browser and go to the intranet address that will be provided by FSIS's Automated Information Systems Division. This address may then be added to the "Favorites" pull-down menu for easy future access.
3. Employees should close the Microsoft Internet Explorer browser when finished accessing LEARN for security reasons.

B. What will the user see upon entering the LEARN application?

1. Inspection program personnel and circuit supervisors will see a screen with two large blocks: "Find a single establishment," or "List all establishments in a circuit."

2. If the user is looking for information for a specific establishment, he or she will select the “Find a single establishment” block and then enter the establishment number. Sample information for that establishment will be listed in order of date posted. The user will then click on the desired sample to link to a detailed report of the information for that sample.
3. The second block on the opening screen, “List all establishments in a circuit,” is tailored for circuit supervisors and patrol inspectors who would like to see the results of various establishments at a time without having to enter the establishment number for each establishment in his or her circuit or patrol one by one on the single establishment block. This option provides sample information for all the establishments in the selected circuit. It also offers filters for the user to narrow the list to a type of establishment (meat, poultry, egg products, import, or all), and a particular type of result (e.g. residues, ready-to-eat micro, food chemistry). As in the single establishment option, the user may see a detailed report of a specific sample available by clicking that sample
4. District, Technical Service Center, and headquarters users will see a different initial screen that is designed for their needs. This screen offers the user the option to view the results of a single establishment only, the results for all establishments in a given circuit or district, or all establishments in the country. If the “Individual Establishment Results” option is selected, a second screen is displayed for the user to specify the establishment number. If the circuit, district, or management option is selected, the second screen obtained allows the user to narrow the list of results obtained to a particular type of establishment, type of result, and when the results were posted. Once the list of individual samples meeting the selection criteria are displayed, the user can see a detailed report of a specific sample by clicking on that sample’s type.

IX. POLICY

A. What do inspection program personnel do with the information/results?

1. Inspection program personnel should immediately provide the information to the establishment management and take any necessary action according to the appropriate regulations and directives.
2. For negative residue results, inspection program personnel should notify the establishment management and release the carcass or product, when applicable. For positive but not violative and violative residue results, inspection program personnel may notify the establishment management but are not to take any enforcement action until directed by the Technical Service Center.

3. The LEARN application will automatically e-mail sample information to the establishment, if the establishment has provided FSIS with an e-mail address on FSIS Form 10,230-2. However, inspection program personnel will provide establishment management with the sample information as well.

NOTE: Sample information may only be provided to the establishment from which the sample was collected.

B. What do compliance officers do with the information/results?

Compliance Officers will have access to Federal establishment laboratory sample information and will be responsible for raw ground beef sample information submitted under the retail ground beef sampling program for *E. coli* O157:H7. Instructions for accessing these results will be issued separately. Compliance officers should notify the retail establishment from which the sample was collected. Retail stores do not currently have the option to receive their results via electronic mail.

C. What if there are problems accessing the intranet page?

Program personnel expecting sample information, and having problems accessing the intranet page, should contact either their circuit supervisor (CS) or district office (DO). The CS or DO may be able to access the page and provide the sample information needed.

D. Can establishments access their own sample information?


Establishments may not access this intranet page. However, an establishment may have their sample information e-mailed to them by completing FSIS Form 10,230-2 (available from the district office) and faxing it to Office of Public Health and Science. The sample information will be e-mailed to the establishment at the same time it is posted to the intranet page.

E. How will State-inspected establishments receive their results from FSIS laboratories?

State-inspected establishments, for which FSIS laboratories analyze samples, do not currently have the option to receive their results via electronic mail. Therefore, each State has identified a State official to whom sample information may be e-mailed so that the sample information can be provided to the State-inspected establishment.

X. GUIDANCE

Contact the Technical Service Center for further information and guidance regarding the LEARN application.

A handwritten signature in black ink, appearing to read "Philip S. Deffen". The signature is written in a cursive style with a large initial "P".

Deputy Administrator
Office of Policy, Program Development
and Evaluation

United States Department of Agriculture
Food Safety and Inspection Service
Room 0157-South Building
Washington, DC
20250

OFFICIAL BUSINESS
Penalty for Private Use, \$300

FIRST-CLASS MAIL
POSTAGE & FEES PAID
USDA-FSIS
Permit No. G-42

4151110
4538

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

10,240.4

10/2/03

Verification Procedures for the *Listeria monocytogenes* Regulation and Microbial Sampling of Ready-to-Eat (RTE) Products for the FSIS Verification Testing Program

PART I -- GENERAL

I. PURPOSE

This directive provides Consumer Safety Inspectors (CSIs) and Consumer Safety Officers (CSOs) with instructions for verifying whether establishments are complying with the regulations in 9 CFR part 430, *Requirements for Specific Classes of Product* (Attachment 5). In addition, this directive includes verification procedures for ready-to-eat (RTE) products other than those applicable to 9 CFR part 430.

NOTE: This document references a number of resources. CSIs and CSOs will receive these resources on a disk. The directive itself, without the resources, contains all the information that CSIs and CSOs need to verify the sections of 9 CFR 430 relating to the control of *Listeria monocytogenes* (*L. monocytogenes*) in post-lethality exposed RTE meat and poultry products.

II. CANCELLATION

FSIS Directive 10,240.3, dated 12/9/02

III. REASON FOR REISSUANCE

To provide verification instructions for 9 CFR Part 430 and to clarify the current sampling instructions.

IV. REFERENCES

FSIS Directive 5000.1, Revision 1, dated 05/21/03
FSIS Directive 5400.5, dated 11/21/97
FSIS Directive 8080.1, Revision 3, dated 1/19/00
FSIS Directive 10,200.1 dated 7/19/01

DISTRIBUTION: Inspection Offices; T/A Inspectors;
Plant Mgt; T/A Plant Mgt; TRA; ABB; TSC; Import Offices

OPI: OPPD

Title 9 Code of Federal Regulations (CFR) Part 416
Title 9 CFR Part 417
Title 9 CFR Part 430
Title 21 United States Code (U.S.C.) parts 453 and 601

V. BACKGROUND

On June 6, 2003, the Food Safety and Inspection Service (FSIS) published a final rule (68 FR 34207) that amended its regulations to require that official establishments that produce certain RTE meat and poultry products prevent product adulteration by the pathogenic environmental contaminant *L. monocytogenes*. In particular, 9 CFR 430.1 sets out definitions of terms. 9 CFR 430.4(a) states that *L. monocytogenes* is a hazard that an establishment producing a RTE product that is exposed to the environment must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. It also states that RTE product is adulterated if it contains *L. monocytogenes* or if it comes into direct contact with a food contact surface that is contaminated with *L. monocytogenes*. 9 CFR 430.4(b) sets out three alternatives that establishments producing post-lethality exposed RTE product are to choose from in order to meet the requirements of 9 CFR 430.4(a). CSIs will have verification responsibilities related to the regulatory requirements of 9 CFR 430.4(b).

PART II --- CSI VERIFICATION RESPONSIBILITIES

CHAPTER I CSI Responsibilities for Verifying Compliance with 9 CFR part 430

Upon receipt of this directive, IICs are to hold an awareness meeting with the establishment management and ask them whether they produce an RTE product that is exposed to the environment after the initial lethality step. The establishment is not required to comply with 9 CFR Part 430 if the RTE products produced in the establishment are not exposed to the environment after the lethality step.

If the establishment is producing post-lethality exposed products, the CSI should ask establishment management which alternative they have chosen for each post-lethality exposed RTE product produced by the establishment. Also, the CSI is to inform the establishment management that, as set out in 9 CFR 430.4(c)(7), verification results that demonstrate the effectiveness of the measures the establishment employs are to be made available upon request.

CSIs, using the appropriate 03 procedure, are to verify that the establishment is meeting the requirements of the alternative that it has chosen. If the establishment decides to produce different products using different alternatives, the CSI should verify that the establishment meets the requirements for each of the alternatives selected, for each of the post-lethality exposed RTE products.

If an establishment is producing post-lethality exposed products and has failed to attempt to meet the requirements of **any** of the alternatives, the CSI should contact the District Office (DO) for the issuance of a Notice of Intended Enforcement Action (NOIE).

NOTE: Attachments 1-4 provide flowcharts that set out the requirements of 9 CFR part 430.

A. What are the regulatory requirements of 9 CFR 430.4(b)(1), Alternative 1?

*Use of a post-lethality treatment (which may also be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product AND an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*.*

B. How do CSIs verify compliance with the requirements in Alternative 1?

To verify compliance, CSIs are to follow the methodology from FSIS Directive 5000.1, Revision 1 when seeking answers to questions such as:

1. Is the post-lethality treatment (which may be an antimicrobial agent) incorporated in the HACCP plan?

2. Does the establishment have validation data for the post-lethality treatment in accordance with 9 CFR 417.4?

3. Is the establishment implementing the post-lethality treatment as described in the HACCP plan?

4. Has the establishment incorporated the use of the antimicrobial agent or process to suppress or limit the growth of *L. monocytogenes* in its HACCP plan, its Sanitation SOPs, or a prerequisite program?

NOTE: If CSIs have questions regarding the validation data, they should contact the Technical Service Center (TSC) or a CSO through supervisory channels about the adequacy of the establishment's validation data.

C. How do CSIs document noncompliance?

If the answers to any questions in B. above or similar questions are "no", CSIs are to issue a FSIS form 5400-4, Noncompliance Record (NR) under the appropriate 03 ISP code as described in FSIS Directive 5000.1, Revision 1 and reference 9 CFR 430.4(b)(1) and the appropriate section of 417 (for HACCP and prerequisite programs) or 416.14 (for Sanitation SOP). CSIs are to verify that the establishment takes corrective and preventive action to bring itself into compliance with 9 CFR Part 430. Such actions may include a reassessment of the HACCP plan and the establishment's choice of another alternative.

D. What are the regulatory requirements of 9 CFR 430.4(b)(2), Alternative 2?

*Use of either a post-lethality treatment (which may be an antimicrobial agent or process) that reduces or eliminates microorganisms on the product OR an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes**

Choice 1 - An establishment that produces post-lethality exposed product that selects this alternative and chooses to use a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product:

OR

Choice 2 - An establishment that produces post-lethality exposed product and that selects this alternative and chooses to use an antimicrobial agent or process that suppresses or limits growth of *L. monocytogenes*.

E. How do CSIs verify compliance with the requirements in Alternative 2?

When verifying compliance with Alternative 2, CSIs are to seek answers to the questions from paragraph B. Alternative 2 is based on the same requirements as Alternative 1, **except** that the establishment can choose to just have a post-lethality treatment that meets the requirements of B. 1-3 above (Choice 1), **or** to just use an antimicrobial agent or process to suppress or limit the growth of *L. monocytogenes* throughout the shelf life of the product that meets the requirements of B. 4 above (Choice 2). **Also**, if the establishment chooses Choice 2, the CSI should seek answers to the following:

Does the establishment's testing for verifying the on-going effectiveness of their sanitation procedures:

1. provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism?
2. identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism?
3. state the frequency with which testing will be done?
4. identify the size and location of the sites that will be sampled?
5. include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes*, or an indicator organism, is maintained?

F. How do CSIs document noncompliance?

If the answers to any of the questions or similar questions are "no", CSIs are to issue a FSIS form 5400-4, Noncompliance Record, NR under the appropriate ISP code as described in FSIS Directive 5000.1, Revision 1 and reference 9 CFR 430.4(b)(2) and, depending where the use of the antimicrobial agent or process is addressed, either the appropriate section of 9 CFR 417 (for HACCP or prerequisite programs) or the appropriate section of 416 (Sanitation SOP). CSIs are to verify that the establishment takes corrective and preventive action to bring itself into compliance with 9 CFR part 430. Such actions may include a reassessment of the HACCP plan and the establishment's choice of another alternative.

G. What are the regulatory requirements of 9 CFR 430.4(b)(3), Alternative 3?

Use of sanitation measures only

H. How do CSIs verify compliance with the requirements in Alternative 3?

To determine compliance, CSIs are to seek answers to questions such as:

Does the establishment that produces post-lethality exposed product and that selects this alternative have on-going verification testing procedures that are designed to:

1. have sanitation measures incorporated in its HACCP plan, Sanitation SOP, or other prerequisite program?
2. test food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism?
3. identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of food contact surfaces for *L. monocytogenes* or an indicator organism?
4. state the frequency with which the testing will be done?
5. identify the size and location of the sites that will be sampled?
6. include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes*, or of an indicator organism, is maintained?

Also, does an establishment producing a deli product or a hotdog product:

1. verify that its corrective actions are effective with respect to sanitation after an initial positive in the post-lethality processing environment are effective by follow-up testing that includes a targeted test of the specific site on the food contact surface area as necessary to ensure effectiveness of the corrective actions?
2. hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result, during this follow-up testing, if the establishment obtains a second positive test for *L. monocytogenes*, or an indicator organism?
3. sample and test the lots for *L. monocytogenes* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes*,

in order to be able to release into commerce the lots of product that may have been contaminated with *L. monocytogenes*?

4. document the results of the testing?

5. rework the held product using a process that is destructive of *L. monocytogenes* or the indicator organism?

I. How do CSIs document noncompliance?

If the answers to any the questions or similar questions are “no”, CSIs are to issue a FSIS form 5400-4, Noncompliance Record, NR under the appropriate ISP code as described in FSIS Directive 5000.1, Revision 1 and reference 9 CFR 430.4(b)(3) and, depending where the use of the antimicrobial agent or process is addressed, either the appropriate section of 9 CFR 417 (for HACCP or prerequisite programs) or the appropriate section of 416 (Sanitation SOP). CSIs are to verify that the establishment takes corrective and preventive action to bring itself into compliance with 9 CFR Part 430. Such actions may include a reassessment of the HACCP plan to determine whether the decisions made in the hazard analysis regarding the use of the prerequisite program remain valid.

CHAPTER 2 CSIs Responsibilities in Verifying 9 CFR of 430.4(e)

A. What are the regulatory requirements of 9 CFR 430.4(e)?

9 CFR 430.4(e) states: *“An establishment that controls L. monocytogenes by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.”*

B. How do CSIs verify compliance with this regulatory requirement?

The CSI should verify that the establishment has documented that the labeling claim is accurate, that the establishment has data to support the claim, and that the establishment has a sketch label approval on file.

If the CSI has concerns about the validation data supporting the claim, he or she should contact the TSC or a CSO through supervisory channels for technical information. If the establishment does not have data to support the claim, the noncompliance would be documented on an NR using the appropriate HACCP procedure code and reference 430.4(e) and 417.5.

CHAPTER 3 CSIs Responsibilities For Collecting Samples of RTE Product

A. How do CSIs collect samples of RTE Products?

NOTE: The following instructions will apply until FSIS has Alternative and production volume information available to develop the new risk-based RTE sampling program. At that time this directive will be revised and any additional issuance(s) provided.

1. When the Office of Public Health and Science (OPHS) schedules a RTE sample to be taken at an establishment, the CSI receives FSIS Form 10,210-3, "Requested Sample Programs." Once the form is received, the CSI **is to always** collect a RTE product sample.

2. If a specific product is not pre-selected for sampling in Block 18 of the sample request form, the CSI should sample products based on the following priority:

a. Post-Lethality Exposed RTE Products under Alternative 3:

1. Deli meats
2. Hotdogs
3. Deli salads, pate, meat spreads
4. other product

b. If no post-lethality exposed RTE products are produced using Alternative 3 criteria, then sample post-lethality exposed RTE products using Alternative 2 criteria in the following order:

1. Sample product produced using only a growth inhibitor
2. Sample product produced using post-lethality treatment

c. If no post-lethality exposed RTE products are produced using Alternative 3 or 2 criteria, then sample post-lethality exposed RTE products using Alternative 1 criteria.

d. If no post-lethality exposed RTE products are produced, then sample any RTE product that is not produced using an antimicrobial agent or process and likely will be used as a deli-type item, such as a cook-in-bag roast beef.

e. If none of the above is available, select any other RTE product.

Again, most importantly, CSIs are to collect a RTE sample.

3. CSIs are to verify that all product represented by the sample (i.e., the sampled lot) is held by the establishment, should it elect to do so.

4. If possible, **only** collect and mail the samples from the establishment's current day's production that has passed the establishment's pre-shipment record review (see 9 CFR 417.5(c)). If not possible, such as in establishments where production is held off-site before completion of the pre-shipment record review, or the pre-shipment record review is performed at a later date, but there are no additional lethality or other pathogen control steps, collect samples of the current day's production, refrigerate or freeze them, keep them in a secure location, and postpone mailing the samples until the pre-shipment record review is complete, and the product is eligible for shipment. After the establishment completes the pre-shipment record review, CSIs should prepare the samples to be sent to the laboratory on the next available Federal Express pickup day.

5. Complete all requested information in Part II of the FSIS form 10,210-3. The FSIS laboratories will discard any samples with incomplete forms. Record an unscheduled 05B02 on the procedure schedule.

6. CSIs will be provided product sample status information and results through the LEARN System (see FSIS Directive 10,200.1). CSIs should provide this information to establishment management even if the establishment receives e-mail notifications from OPHS.

7. When necessary, program personnel, other than CSIs, collect samples from food contact surfaces.

CHAPTER 4 CSI Responsibilities Regarding Enforcement

FSIS makes the following determinations regarding adulteration based on the circumstances:

A. Pathogen in a product sample.

1. If any RTE product sample collected by FSIS or by the establishment (after pre-shipment review) tests positive for a pathogen of public health concern, product in the sampled lot is adulterated. CSIs are to issue an NR using the appropriate 03 ISP code and FSIS will request a recall if any product in the sampled lot has been shipped.

NOTE: If the positive result is from an establishment test and the establishment held the affected product, CSIs are not to issue an NR unless the establishment fails to comply with 2 - 3 below.

2. CSIs are to verify that establishments implement corrective actions in accordance with 9 CFR 417.3(a) (under HACCP), 9 CFR 416.15 (under Sanitation SOPs), or 9 CFR 417.4(a)(3) (under prerequisite programs).

3. CSIs are to verify the establishment disposition of the sampled product lot, by verifying that the establishment has documentation to support that potential contamination would be limited to individual production lines and for individual products and by verifying the establishment has destroyed the sampled lot or whether it has reworked the sampled lot with a process that is destructive of *L. monocytogenes*.

B. Pathogen on a food contact surface sample.

1. If a post-lethality exposed RTE food contact surface sample collected by FSIS or by the establishment (after pre-shipment review) tests positive for a pathogen of public health concern, product passing over the surface is adulterated. CSIs are to issue an NR using the appropriate 03 ISP code and FSIS will request a recall if any product in the sampled lot has been shipped.

NOTE: If the positive result is from an establishment test and the establishment held the affected product, CSIs are not to issue an NR unless the establishment fails to comply with 2 - 3 below.

2. CSIs are to verify that establishments implement corrective actions in accordance with 9 CFR 417.3(a) (under HACCP), 9 CFR 416.15 (under Sanitation SOPs), or 9 CFR 417.4(a)(3) (under prerequisite programs).

3. CSIs are to verify the establishment disposition of the sampled product lot, by verifying that the establishment has documentation to support that potential contamination would be limited to individual production lines and for individual products and by verifying the establishment has destroyed the sampled lot or whether it has reworked the sampled lot with a process that is destructive of *L. monocytogenes*.

4. The DO may coordinate scheduling intensified verification sampling through OPHS to verify the establishment's corrective and preventive measures. This sampling should not be initiated until the corrective and preventive measures have been put in place.

NOTE: An establishment may or may not conduct environmental sampling, other than on food contact surfaces, under its HACCP plan, Sanitation SOPs, or a prerequisite program. If the establishment is conducting such sampling, and positive results are received, CSIs are to verify that the establishment takes the appropriate action as outlined in the program under which the sampling is conducted. If the establishment is conducting such sampling, but is not addressing the sampling under HACCP, Sanitation SOPs, or a prerequisite program and CSIs find that such sampling is resulting in persistent positive results, CSIs are to notify the DO. Also, FSIS personnel, other than CSIs, may conduct environmental sampling when necessary and as directed by the DO.

PART III -- CSO Assessment of Compliance with 9 CFR part 430

The CSO should understand the public health risks associated with post-lethality exposed RTE products and processes. Some products and processes pose greater potential risks for *L. monocytogenes* causing human illness and disease in the form of listeriosis than others do. For example, product in alternative 3 likely will present greater risk than product in alternative 2, and product in alternative 2 likely will present greater risk than product in alternative 1. Also, deli product and hotdog product likely will present greater risk than most other product within each alternative. However, other than deli product and hotdog product, deli meat salads and pate/meat spreads likely will present greater risk than other RTE products. Consequently, when considering how to focus verification activity within the establishment when the establishment makes a variety of post-lethality exposed RTE products, more attention should be allotted to the products and processes that present the greatest potential for causing illness and disease.

When CSOs go into an establishment that is producing post-lethality exposed products, they are to conduct a complete comprehensive assessment of the food safety systems in operation. Specifically, CSOs will need to evaluate some design issues relevant only to post-lethality exposed RTE products.

To assess that the establishments have properly addressed the use of a post-lethality step (Alternative 1 or the first choice in Alternative 2), CSOs should review the establishment's HACCP plan and HACCP supporting documentation to verify that post-lethality has been adequately validated so that it prevents, eliminates, or reduces the pathogens of concern on the product to an undetectable level.

If the establishment has based its validation on challenge studies or research articles from scientific publications, the CSOs should assess whether conditions in the establishment, such as ingredients, concentration of antimicrobial agent, pH, moisture, are identical to those found in the challenge studies or research articles from scientific publications. If the conditions are not identical, does the establishment have documentation on file to support that the controls in place are adequate to prevent, eliminate, or reduce to undetectable levels pathogens on the product?

With regard to the use an antimicrobial agent or a process used to suppress or limit the growth of *L. monocytogenes* throughout the shelf life of the product (Alternative 1 or Alternative 2, choice 2), the CSO should assess the documentation in whichever program the use of the antimicrobial agent or process is incorporated (i.e., HACCP, Sanitation SOPs, or prerequisite programs), to determine whether it demonstrates the production of safe product.

With regard to the testing that the establishment is to do if it chooses Alternative 2, choice 2, the CSO should assess the adequacy of how the establishment:

1. tests food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism,
2. identifies the conditions under which the establishment will implement hold-and-test procedures following a positive test of food contact surfaces for *L. monocytogenes* or of an indicator organism,
3. establishes and supports the frequency with which the testing will be done,
4. establishes and supports the size and location of the sites that will be sampled,
5. explains and supports why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of an indicator organism is maintained,
6. chooses the sites that are most likely to be locations to find *L. monocytogenes* or an indicator organism,
7. supports the design of the testing to detect *L. monocytogenes* or an indicator organism.

With regard to the testing an establishment has to do if it chooses Alternative 3, CSOs are to assess all the factors for the testing in Alternative 2 as well as in establishments that produce a deli product or a hotdog product, the adequacy of how the establishment:

1. verifies that corrective actions that it took with respect to sanitation after an initial positive test for *L. monocytogenes*, or an indicator organism on a food contact surface in the post-lethality processing environment were effective by follow-up testing that included a targeted test of the specific site on the food contact surface area as was necessary to ensure effectiveness of the corrective actions,
2. holds lots of product that may have become contaminated by contact with the food contact surface during follow-up testing after the establishment obtains a second positive test,
3. samples and tests the lots for *L. monocytogenes* or an indicator organism using a sampling method and frequency that provided a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes* before releasing into commerce the lots of product that may have been contaminated with *L. monocytogenes*,

4. documents the results of the testing, and

5. reworks held product using a process that is destructive of *L. monocytogenes* or the indicator organism.

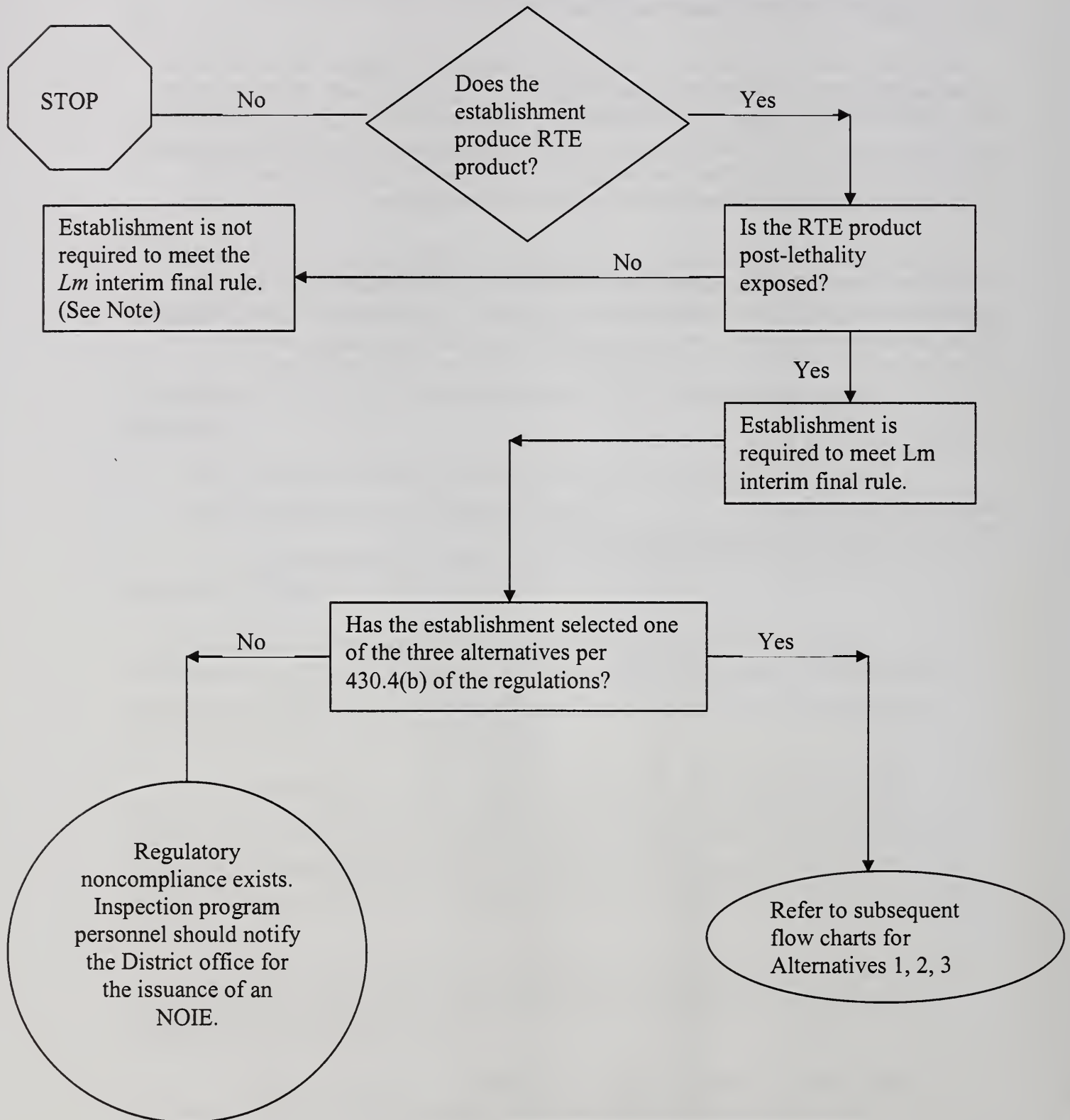
When the CSO completes the comprehensive assessment of all of the food safety systems in operation in the establishment, he/she should complete FSIS form 5000-8, Comprehensive Assessment of the Execution and Design of an Establishment's Food Safety System. The findings listed in this report should support the recommendations made by the CSO that the establishment is in compliance, or that further enforcement action is necessary.

The *Compliance Guidelines to Control Listeria Monocytogenes in Ready-to-Eat Poultry Products* will be provided to all CSIs and CSOs on a disk. These guidelines can be used as references for a better understanding of what industry might be doing to control *L. monocytogenes* in post-lethality exposed RTE products.

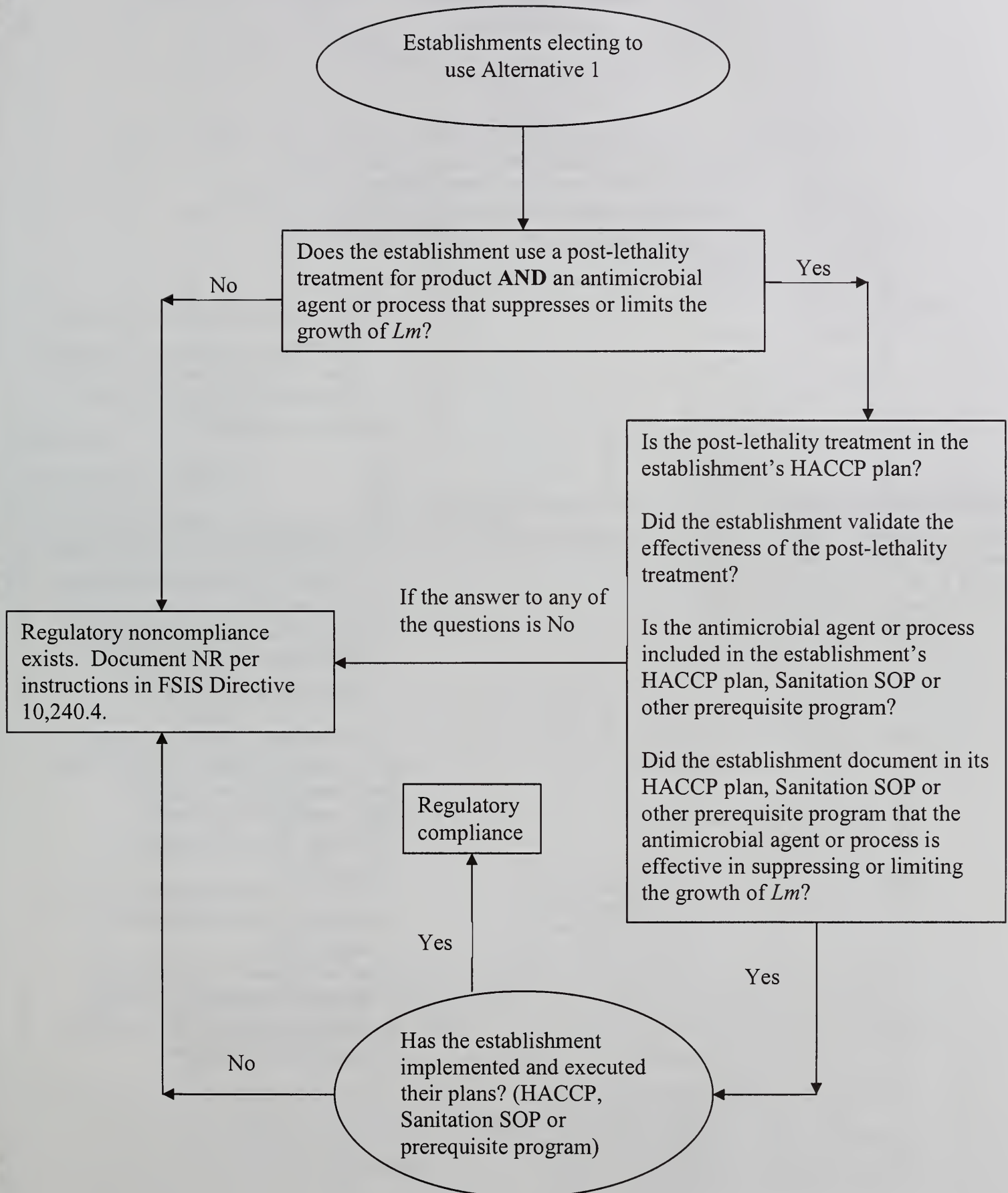


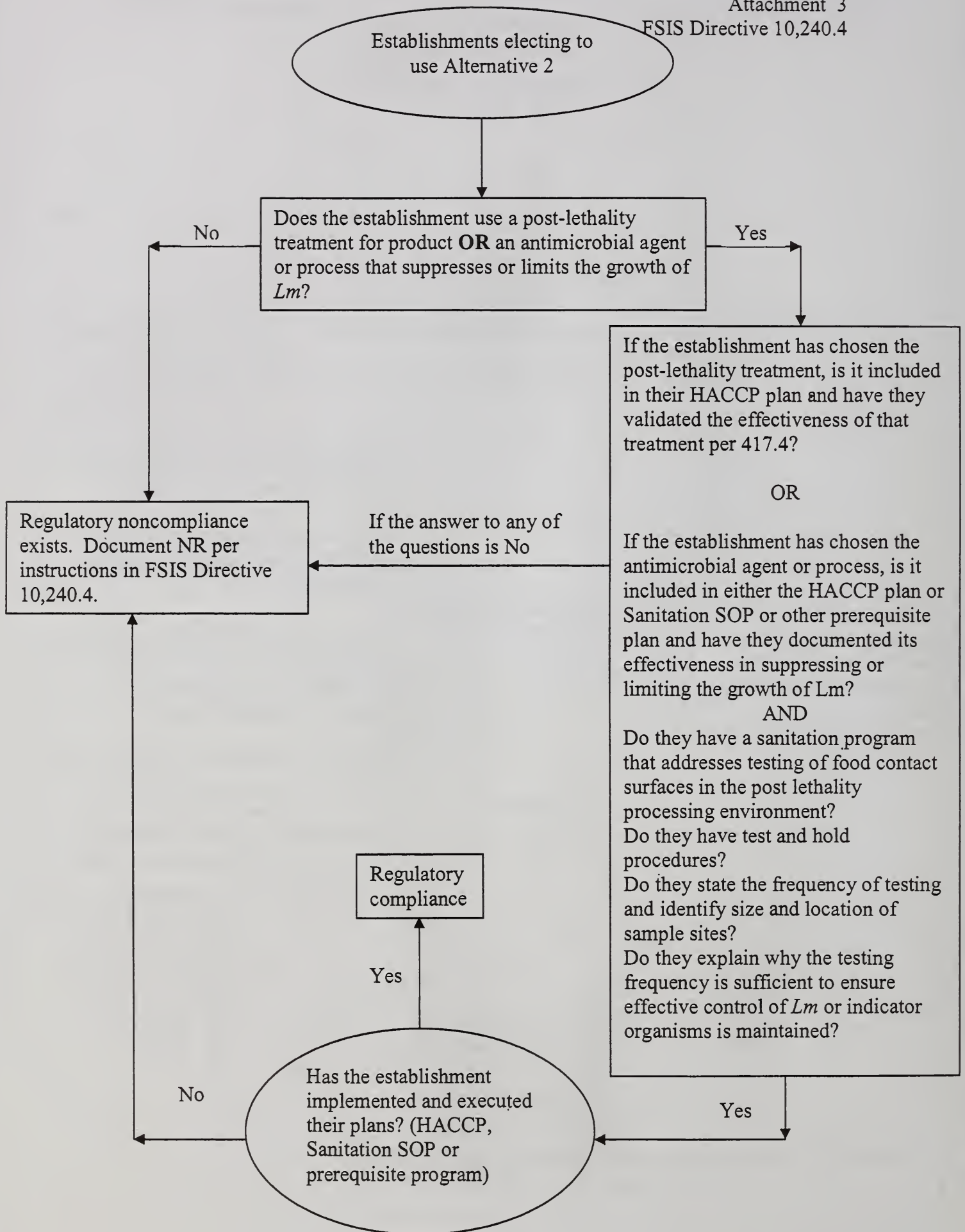
Assistant Administrator
Office of Policy and Program Development

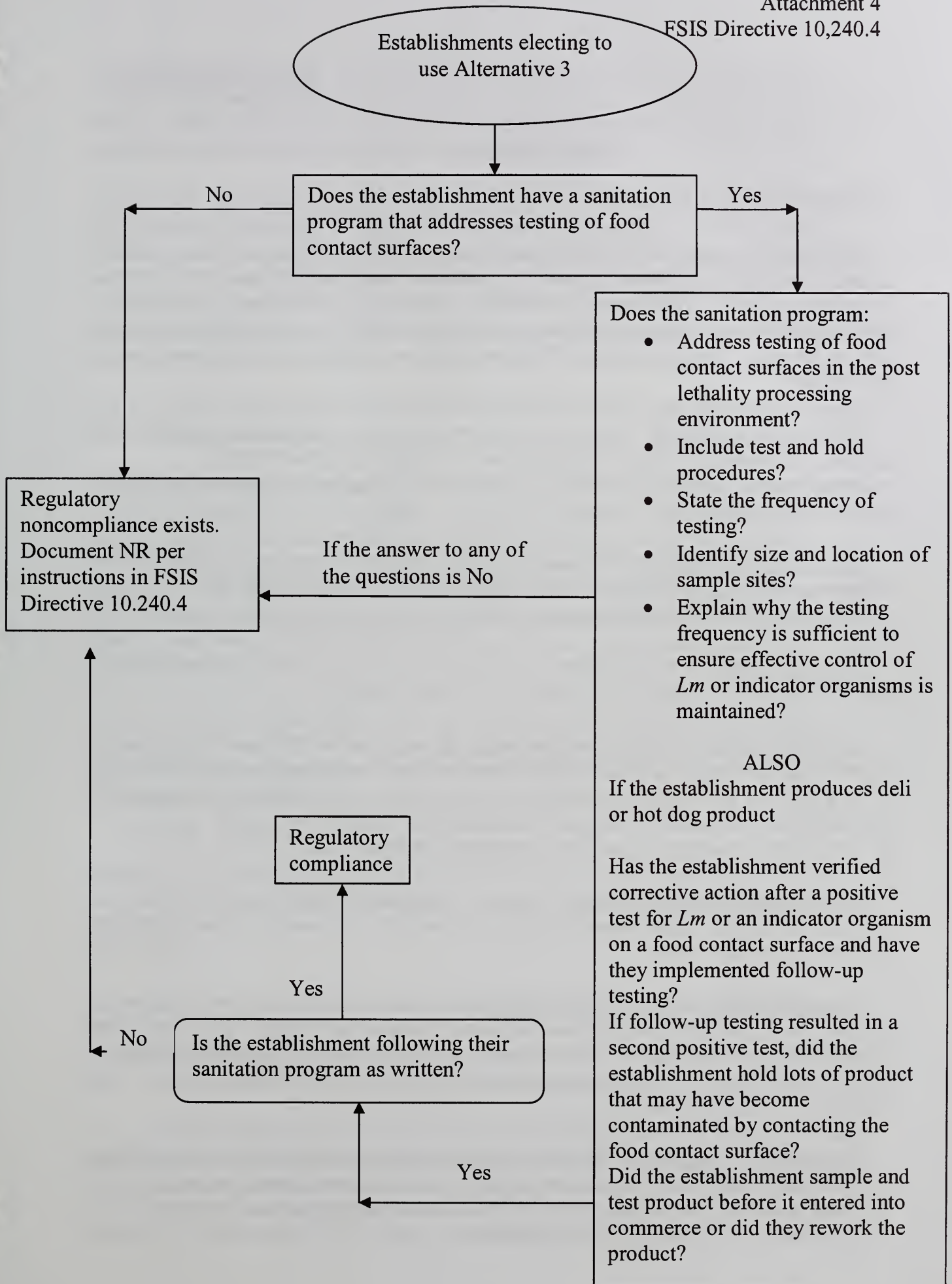
Control of *L. monocytogenes* in
post-lethality exposed RTE
products



Note: FSIS Sampling Verification still applies to RTE products that do not fall under the new regulation.







RTE Regulations

9 CFR 430.1, **Definitions.**

Antimicrobial agent. A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial process. An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes*, in the product throughout the shelf life of the product.

Deli product. A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.

Hotdog product. A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181.

Lethality treatment. A process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Post-lethality exposed product. Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

Post-lethality processing environment. The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment. A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Prerequisite program. A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called "prerequisite" because it is considered by scientific experts to be prerequisite to a HACCP plan.

Ready-to-eat (RTE) product. A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR 317.2(l) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

9 CFR 430.4, *Control of Listeria monocytogenes* in post-lethality exposed ready-to-eat products.

(a) *Listeria monocytogenes* can contaminate RTE products that are exposed to the environment after they have undergone a lethality treatment. *L. monocytogenes* is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. RTE product is adulterated if it contains *L. monocytogenes* or if it comes into direct contact with a food contact surface which is contaminated with *L. monocytogenes*.

(b) In order to maintain the sanitary conditions necessary to meet this requirement, an establishment producing post-lethality exposed RTE product must comply with the requirements included in one of the three following alternatives:

(1) Alternative 1. Use of a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product and an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*. If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit the growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of the post-lethality treatment incorporated in its HACCP plan in accordance with Sec. 417.4. The establishment must document, either in its HACCP plan or in its Sanitation SOP or other prerequisite program, that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*.

(2) Alternative 2. Use of either a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product or an antimicrobial agent or process that suppresses or limits growth of *L. monocytogenes*. If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of a post-lethality treatment incorporated in its HACCP plan in accordance with Sec. 417.4. The establishment must document in its HACCP plan or in its Sanitation SOP or other prerequisite program that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*.

(iii) If an establishment chooses this alternative and chooses to use only an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(iv) An establishment that chooses this alternative and uses a post-lethality treatment of product will likely be subject to more frequent verification testing by FSIS than if it had chosen Alternative 1. An establishment that chooses this alternative and uses an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes* will likely be subject to more frequent FSIS verification testing than if it uses a post-lethality treatment.

(3) Alternative 3. Use of sanitation measures only.

(i) If an establishment chooses this alternative, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(ii) An establishment producing a deli product or a hotdog product, in addition to meeting the requirements of paragraph (b)(3)(i) of this section, must meet the following requirements:

(A) The establishment must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for *L. monocytogenes* or an indicator organism on a food contact surface in the post-lethality processing environment are effective by conducting follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and such additional tests in the surrounding food contact surface area as are necessary to ensure the effectiveness of the corrective actions.

(B) During this follow-up testing, if the establishment obtains a second positive test for *L. monocytogenes* or an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result.

(C) Further, in order to be able to release into commerce the lots of product that may have become contaminated with *L. monocytogenes*, the establishment must sample and test the lots for *L. monocytogenes* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes*. The establishment must document the results of this testing.

Alternatively, the establishment may rework the held product using a process that is destructive of *L. monocytogenes* or the indicator organism.

(iii) An establishment that chooses Alternative 3 is likely to be subject to more frequent verification testing by FSIS than an establishment that has chosen Alternative 1 or 2. An establishment that chooses Alternative 3 and that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products.

(c) For all three alternatives in paragraph (b):

(1) Establishments may use verification testing that includes tests for *L. monocytogenes* or an indicator organism, such as *Listeria* species, to verify the effectiveness of their sanitation procedures in the post-lethality processing environment.

(2) Sanitation measures for controlling *L. monocytogenes* and procedures for antimicrobial agents or processes that suppress or limit the growth of the pathogen may be incorporated either in the establishment's HACCP plan or in its Sanitation SOP or other prerequisite program. When these control procedures are incorporated into the Sanitation SOP or prerequisite program, and not as a CCP in the HACCP plan, the establishment must have documentation that supports the decision in its hazard analysis that *L. monocytogenes* is not a hazard that is reasonably likely to occur.

(3) The establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416.

(4) If *L. monocytogenes* control measures are included in the HACCP plan, the establishment must validate and verify the effectiveness of measures for controlling *L. monocytogenes* included in its HACCP plan in accordance with Sec. 417.4.

(5) If *L. monocytogenes* control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with Sec. 416.14.

(6) If the measures for addressing *L. monocytogenes* are addressed in a prerequisite program other than the Sanitation SOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

(7) The establishment must make the verification results that demonstrate the effectiveness of the measures it employs, whether under its HACCP plan or its Sanitation SOP or other prerequisite program, available upon request to FSIS inspection personnel.

(d) An establishment that produces post-lethality exposed RTE product shall provide FSIS, at least annually, or more often, as determined by the Administrator, with estimates of annual production volume and related information for the types of meat and poultry products processed under each of the alternatives in paragraph (b) of this section.

(e) An establishment that controls *L. monocytogenes* by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.

United States Department of Agriculture
Food Safety and Inspection Service
Printing Management Section
5601 Sunnyside Avenue, Mail Drop 5241
Beltsville, MD 20705-5241

FIRST-CLASS MAIL
POSTAGE & FEES PAID
USDA-FSIS
Permit No. G-42

OFFICIAL BUSINESS
Penalty for Private Use, \$300

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

11,150.1

10/22/92

BLUEPRINT REVIEW POLICY -- QUESTIONS AND ANSWERS

I. PURPOSE

This directive transmits a Questions and Answers Guide regarding blueprint and specifications submittal and approvals. There are six sections of questions and answers. The first regards original blueprint and specification submissions and the second, submissions for changes to previously approved blueprints and specifications. The third and fourth sections deal with the appeal and re-submission process and review difficulties, respectively. Section five addresses the monitoring of facilities and, lastly, section six provides some general questions and answers.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

MPI Regulations, Sections 304.2, 308.2, 308.3 and 381.19,
381.45.
FSIS Directives, 11,010.1, 11,100.1, 11,100.2, and 11,140.1.

V. POLICY

The MPI Regulations require that two sets of complete drawings (blueprints) and four sets of specifications be submitted to the Facilities, Equipment, and Sanitation Division (FESD), Science and Technology, prior to a grant of inspection. Approval is based on a review and evaluation of facility blueprint drawings. Additionally, any changes to official establishments must be approved by FESD, however, only the

DISTRIBUTION: Inspection Offices, T/A Inspectors, Plant Mgt., T/A Plant Mgt., TRA, ABB, PRD, AID

OPI: S&T/FESD

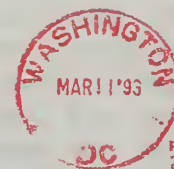
United States Department of Agriculture

Food Safety and Inspection Service

**Washington, D.C.
20250**

**OFFICIAL BUSINESS
Penalty for Private Use, \$300**

MAILED AT
BALTIMORE, MD
DROP SHIPMENT
AUTHORIZATION 26
PRESORTED FIRST-CLASS



U.S. OFFICIAL MAIL

PENALTY
FOR
PRIVATE
USE \$300
P.B. METER
2310263

U.S. POSTAGE

0.24

FIRST CLASS MAIL

37/520MPSLD1594 R1 103-0001
E1

US DEPT OF AGRICULTURE
FOOD & NUTRI INFORMATION CNTR
NAT'L AGRI LIBRARY, RM 304
BELTSVILLE MD 20705-2351



CHANGE TRANSMITTAL SHEET

☐ DIRECTIVE

☐ REVISION

☐ AMENDMENT

☒ OTHER

BLUEPRINT REVIEW POLICY--
QUESTIONS AND ANSWERS

11,150.1

2/2/93

I. PURPOSE

The title of FSIS Directive 11,150.1, dated 10/22/92, has been changed. The attached page contains the new title.

II. CHANGE

The title of FSIS Directive 11,150.1, dated 10/22/92, has been changed to read "Blueprint Review Policy -- Questions and Answers." Please remove the first page of the directive and replace it with the attached page.

III. CANCELLATION

This transmittal sheet is cancelled when the attached page has been incorporated into FSIS Directive 11,150.1.



Acting Director
Regulations Development Unit
Policy Office, PEPS

Attachment

THE HISTORY OF THE

AMERICAN PEOPLE

FROM 1492 TO 1876

BY JAMES OSGOOD

NEW YORK

1876

Vol. I

THE DISCOVERY OF AMERICA

1492-1500

THE FIRST SETTLEMENTS

1500-1600

THE GREAT WESTERN MOVEMENT

1600-1700

THE REVOLUTION

1776-1789

THE CONSTITUTION

1789-1800

THE JEFFERSONIAN ERA

1800-1820

FSIS DIRECTIVE

11,240.1
Rev. 1

11-30-93

CONVERTING LARD OR TALLOW TANK CARS MARKED INEDIBLE TO EDIBLE PRODUCT USE

I. PURPOSE

This directive provides guidelines on converting railroad tank cars from inedible rendered product use to edible rendered product use.

II. CANCELLATION

FSIS Directive 11,240.1, dated 10/18/93

III. [RESERVED]

IV. REFERENCES

MPI Regulations Sections 308.5 and 316.15
FSIS Directive 8800.1, PBIS Implementation Instructions,
dated 11/1/91
FSIS Directive 8820.1, Corrective Action System, dated
3/1/91

V. FORMS AND ABBREVIATIONS

The following will appear as abbreviated in this directive:

IIC	Inspector in Charge
MPI	Meat and Poultry Inspection
PBIS	Performance Based Inspection System
STCC	Standard Transportation Commodity Code

VI. POLICY

FSIS has determined that railroad tank cars may be converted from inedible rendered product use to edible rendered product use provided that acceptable sanitation and inspection procedures are followed.

VII. RESPONSIBILITIES

A. The official establishment should:

1. Have cleaning/reconditioning and inspection procedures approved by and on file with the IIC which include, at a minimum:

a. Name and title of the individual responsible for implementing the cleaning/reconditioning procedure.

b. A description of the cleaning procedure, including type of chemicals to be used and water temperature.

c. A description of the procedures to be used by establishment personnel for inspecting tank cars following the cleaning operation, including inspecting the exterior, interior, and all accessible gaskets and seals of the tank car.

d. Documents which reflect the results of inspections performed by establishment personnel to determine compliance with FSIS requirements for converting tank cars from inedible to edible product use, tank car identification number, any comments, and signature of the person performing the inspection.

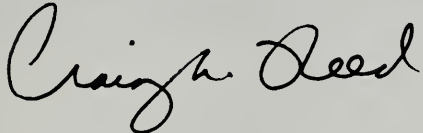
e. A description of the actions that will be taken by the responsible official if cleaning and inspection deficiencies occur.

B. Inspection Personnel:

1. Inspection personnel should not enter the tank car to perform PBIS verification tasks. In lieu of entering the tank car, inspection personnel should observe the parts of the tank car interior which can be adequately illuminated by using a hand held, dry cell powered light, or an electric drop cord, furnished by the establishment. Electrical drop cords must have shatter proof bulbs, and be properly insulated and grounded to eliminate electrical shock hazards. Observation of the tank car interior can be accomplished by viewing the illuminated areas through the tanker hatch. Converted tank cars should not have exposed heating elements, and should be otherwise suitable for edible product use. ■

2. Use PBIS Code 09B01a1 for records evaluation and PBIS Code 09B01a2 for inspection verification. ■

3. Use appropriate unscheduled task code as indicated in FSIS Directive 8800.1. If a deficiency is observed, apply the Corrective Action System as described in FSIS Directive 8820.1.

A handwritten signature in black ink, appearing to read "Craig Reed". The signature is written in a cursive, flowing style.

Deputy Administrator
Inspection Operations

United States Department of Agriculture

Food Safety and Inspection Service

**Washington, D.C.
20250**

OFFICIAL BUSINESS

Penalty for Private Use, \$300

FIRST CLASS MAIL

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

11,540.1

9-17-93

USE OF CERTAIN VEHICLES AS REFRIGERATION OR DRY STORAGE FACILITIES

I. PURPOSE

This directive provides: (1) guidance to inspection personnel for approval of truck trailers, railroad boxcars and shipboard containers which are used as refrigeration or dry storage facilities, (2) for the immediate use of such vehicles and containers if they meet the guidelines in this directive, and (3) information to assist inspectors in review of the blueprint specifications for these vehicles.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

MPI Regulations 304.2, 308.7, 308.9, 308.10, 308.12, 381.19, 381.47(f) and 381.65(a)
FSIS Directive 5400.1, Rev. 2, dated 1/29/92
FSIS Directive 8820.1, Rev. 1, dated 3/1/92
FSIS Directive 8830.1, dated 3/1/91
FSIS Directive 11,000.1, dated 3/21/86
FSIS Directive 11,000.2, dated 4/28/87

V. [RESERVED]

VI. POLICY

A. FSIS is responsible for inspecting meat and poultry establishment premises, facilities and equipment to ensure that they are clean and sanitary and will not adulterate meat or

poultry products. Section 8 of the Federal Meat Inspection Act and section 7 of the Poultry Products Inspection Act provide that each official establishment slaughtering livestock or poultry, or preparing meat or meat food products, or processing poultry products for commerce or otherwise subject to inspection under these Acts, shall operate in accordance with sanitary practices.

B. Section 308.7 of the meat inspection regulations states that product storage rooms, compartments, places, equipment and utensils shall be kept clean and in sanitary condition. It further provides that there shall be no handling or storing of materials which create an objectionable condition in rooms, compartments, or places where any product is prepared, stored or handled. Under section 308.9 of the meat inspection regulations, product shall be protected from contamination from any source during storage, loading, or unloading at and transportation from official establishments. Finally, section 381.65(a) of the poultry products inspection regulations states that operations and procedures involving the processing, other handling, or storing of any poultry product shall be performed in a sanitary matter, resulting in products which are not adulterated.

C. The MPI Regulations also require that product storage areas be kept in good repair, dry, orderly, sanitary and otherwise adequate for the type and quantity of material being handled and used in such a way that meat and poultry products, and/or packaging materials do not become contaminated prior to use.

D. Truck trailers, railroad boxcars or shipboard containers are being used by some establishments as storage facilities. The MPI Regulations do not provide any specific requirements governing the use of truck trailers, railroad boxcars or shipboard containers as refrigeration and/or dry storage facilities. They are special purpose vehicles or containers designed to hold product, properly packed, during transportation. Use of these vehicles to store product at the establishment is discouraged. If they are used to store product and packaging material at the official establishment, they are considered part of that establishment and must meet all applicable facility and sanitation requirements of the regulations.

E. The use of a truck trailer, railroad boxcar or shipboard container for storage of product at an establishment constitutes a modification to the facility which requires prior approval from the Facilities, Equipment and Sanitation Division (FESD), Science and Technology. In the past, blueprints and specifications submitted by the establishment for the use of these vehicles and containers have been incomplete, causing delays in their approval by FESD. The following information gives guidance in preparing

specifications and allows inspectors to immediately approve the use of these vehicles and containers if they meet all of the guidelines in this directive.

VII. Management Responsibilities

To permit inspectors to provide on-site approval of facility modifications consisting of truck trailers, railroad boxcars or shipboard containers for holding meat product, poultry products or packaging materials, establishment management must ensure that:

A. truck trailers, railroad boxcars or shipboard containers used to store meat and poultry products, other food products or packaging materials meet all applicable facility and sanitation requirements of the regulations,

B. a new FSIS Form 5200-5 is submitted to the inspector; the new Form 5200-5 must include either a detailed description of the modifications for the vehicle or container and/or a statement in the specifications that the vehicle or container meets all of the guidelines set forth in Paragraphs VII and VIII of this directive, and

C. sanitary conditions and handling practices are followed, such as:

1. storing meat or poultry products, other food products or packaging materials at least one foot off the floor and away from walls of truck trailers, railroad boxcars or shipboard containers for ease of cleaning and inspection or moving them frequently to facilitate cleaning and inspection, and

2. covering meat and poultry products, other food products or packaging materials held in truck trailers, railroad boxcars or shipboard containers.

VIII. Inspector Responsibilities

A. Approval Procedures and Criteria for Approval

1. The inspector shall assure, prior to approval of the use of such vehicle or container, that the establishment has properly completed a FSIS Form 5200-5, Submission and Approval of Plans and Specifications, and documented in the specifications that they have met the guidelines in Paragraphs VII and VIIIA2.

2. When approving the use of truck trailers, railroad boxcars or shipboard containers as refrigeration or dry storage facilities, the inspector shall ensure that:

a. the vehicle or container is on a full dimension concrete pad, skirted or sealed to the concrete pad with skirting having an access door for inspection. An adequate clean-up hose connection must be nearby,

b. there is adequate space around all sides of the vehicle or container to facilitate easy access and proper cleaning,

c. grooved floors are thoroughly cleaned, then covered or filled so that the new floor is flat, without grooves or space between the original and new floor, and the new floor is properly sloped for drainage with the drain properly connected to the drain line,

d. walls and ceilings are in good repair and covered with materials that are durable, rigid, smooth and impervious to moisture, and easily cleaned, without overhead appurtenances, such as exposed structures or canvas ducting,

e. the body of the vehicle or container is sealed to the building if it is positioned next to the building,

f. the refrigeration unit is properly connected to the exterior of the vehicle or container and is sealed and properly maintained,

g. product is thoroughly pre-cooled before storage in the vehicle or container,

h. the vehicle or container is equipped with shielded overhead lights that supply at least 20 foot candles of illumination throughout the interior,

i. boxes are stacked to obtain maximum and uniform cooling with the type of air delivery and refrigeration system used, and

j. passageways are maintained between rows and are spaced at least 1 foot away from the walls to allow inspection and cleaning.

3. The inspector shall monitor meat and poultry products and packaging materials stored in truck trailers, railroad boxcars or shipboard containers. During the inspection, the inspector shall ensure that:

a. meat and poultry products, or packaging materials held in truck trailers, railroad boxcars or shipboard containers are stored the same as if they were in permanent storage facilities,

b. truck trailers, railroad boxcars or shipboard containers are clean, dry, orderly, sanitary, and otherwise adequate for the type and quantity of material being handled, and

c. neither stored meat and poultry products, other food products, nor packaging materials held in truck trailers, railroad boxcars or shipboard containers come in direct or indirect contact with rain, dust, water, vapor, or other damp conditions, or pests, such as insects, birds, and rodents, or airborne contaminants.

B. When Contamination is Suspected

1. In slaughter establishments, if the inspector finds carcasses or parts or packaging materials stored in truck trailers, railroad boxcars or shipboard containers in an unsanitary manner which may cause contamination, the inspector shall attach a "U.S. Rejected" tag to the truck trailer, railroad boxcar, or shipboard container at entry or exit points.

2. In slaughter establishments, if carcasses or parts or packaging materials become contaminated as a result of storage in truck trailers, railroad boxcars or shipboard containers, the inspector shall:

a. tag the truck trailer, railroad boxcar or shipboard container with a "U.S. Rejected" tag at the entry point,

b. tag the carcasses or parts or packaging materials with a "U.S. Retained" tag,

c. reinspect the carcasses or parts or packaging materials after the establishment indicates they have taken appropriate reconditioning or corrective action,

d. remove the "U.S. Rejected" tag from the truck trailer, railroad boxcar or shipboard container if the corrective action is acceptable, and

e. remove the "U.S. Retained" tag from the product if the product is determined to be wholesome.

3. In processing establishments, if the inspector finds meat and poultry products, other food products or packaging materials stored in temporary truck trailers, railroad boxcars or shipboard containers in an unsanitary manner, the inspector shall take corrective action as specified in FSIS Directive 8820.1, Rev. 1 and FSIS Directive 8830.1.

C. When Unapproved Vehicles are Used as Storage Containers

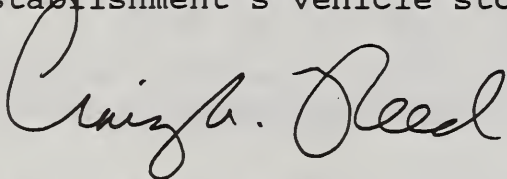
1. If the inspector finds meat and poultry products, other food products or packaging materials being stored in an unapproved truck trailer, railroad boxcar or shipboard container in a slaughter establishment, the inspector shall:

a. tag the truck trailer, railroad boxcar or shipboard container with a "U.S. Rejected" tag at the entry point to prohibit further such use of that facility, until ascertaining that all applicable inspection requirements for that facility have been met, and

b. tag the product held inside the truck trailer, railroad boxcar or shipboard container with a "U.S. Retained" tag until the establishment has taken corrective action, as necessary, prior to reinspection and appropriate disposition of the product by the inspector.

2. If the inspector finds an unapproved truck trailer, railroad boxcar or shipboard container being used to store meat and poultry products, other food products or packaging materials in a processing establishment, the inspector shall take corrective action as specified in FSIS Directive 8820.1, Rev. 1 and FSIS Directive 8830.1.

Establishments have six (6) months from the date of this directive to submit amended blueprints to FESD reflecting the establishment's vehicle storage facilities.



Deputy Administrator
Inspection Operations

THE CIRCUIT

THE CIRCUIT

THE CIRCUIT

THE CIRCUIT

THE CIRCUIT

THE CIRCUIT

THE CIRCUIT

THE CIRCUIT

THE CIRCUIT

United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C.
20250

OFFICIAL BUSINESS
Penalty for Private Use, \$300

FIRST CLASS MAIL

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, D.C.

FSIS DIRECTIVE

11,550.1

9/21/93

COMMON AREAS IN FEDERALLY INSPECTED ESTABLISHMENTS

I. PURPOSE

This directive provides guidelines to inspectors to ensure that contact with unsanitary common areas does not cause product to become adulterated. Common areas are areas in meat and poultry establishments which are used in common by employees of two or more federally inspected establishments.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

MPI Regulations, Sections 305.1, 308.3(a), and 318.2(d)
FSIS Directive 5400.1, Rev. 2, dated 1/29/92
FSIS Directive 8820.1, Rev. 1, dated 3/1/91
FSIS Directive 8830.1, dated 3/1/91
FSIS Directive 11,150.1, dated 10/22/92

V. FORM

The following form will be referenced in this directive:

FSIS Form 5200-5, Submission and Approval of Plans and Specifications

VI. POLICY/BACKGROUND

A. FSIS is responsible for inspecting meat and poultry establishment premises, facilities and equipment to ensure that they are clean and sanitary and will not adulterate meat or

poultry products. Section 8 of the Federal Meat Inspection Act and section 7 of the Poultry Products Inspection Act provide that each official establishment slaughtering livestock or poultry, or preparing meat or meat food products, or processing poultry products for commerce or otherwise subject to inspection under these Acts, shall operate in accordance with sanitary practices.

B. FSIS is concerned about meat and poultry products that may become contaminated from foreign material and/or pathogenic bacteria. Section 305.1 of the MPI Regulations permits persons operating as separate entities in the same building to operate under his or her own grant of inspection. Under such circumstances, all separate entities in the same structure operating under a grant of inspection are required to comply with the Federal Meat Inspection Act and regulations in both their own establishments and in common areas, including hallways, stairways and elevators. FSIS currently permits limited common areas in federally inspected meat and poultry establishments.

C. Because the use of common areas by different establishment employees provides greater potential for unsanitary conditions due to "shared" responsibility for cleanliness, such areas are a source of potential contamination of meat and poultry products and use of common areas should be carefully controlled. FSIS limits the use of common areas to areas used primarily for the movement of packaged product and people, areas used primarily to house utilities, and the USDA office. These areas should be arranged so that employees of one establishment do not need to pass through the non-common facilities of another establishment, such as a processing room, to reach a common area or part of their own facilities.

D. The MPI Regulations require that each applicant for inspection submit detailed drawings and specifications of the facility to the FSIS Administrator before inspection can be granted. Drawings and specifications must also be submitted for existing facilities in which remodeling, modification or expansion is planned. FSIS's Facilities, Equipment and Sanitation Division (FESD) reviews and evaluates the drawings and specifications of proposed new facilities or the modification or replacement of existing facilities. FESD will not approve an arrangement of common areas which requires the employees of one establishment to pass through the non-common facilities of another establishment to reach a common area or part of their own facilities.

VII. Inspection Procedures

A. The inspector shall inform all entities in the same structure operating under separate grants of inspection that each entity is responsible for keeping common areas in the structure clean and sanitary.

B. The inspector should ensure that common areas are limited to:

1. areas primarily used for movement of packaged product and people, such as hallways, stairways, elevators, shipping and receiving docks or areas, and welfare facilities,

2. areas used primarily to house utilities, such as boiler rooms, compressor rooms, refrigerator rooms, and electrical control rooms, and

3. the USDA office.

C. If the inspector finds that the arrangement of the facilities requires employees of one establishment to pass through another establishment's non-common area, such as a processing room, to reach a common area or part of their own facilities, the inspector shall:

1. inform management of all facilities sharing the common areas of the situation, and

2. inform management of all facilities that share the common areas that each must simultaneously submit to FESD a completed FSIS Form 5200-5 and an updated set of drawings and specifications showing the arrangement of the common areas.

VIII. Inspector Responsibilities

A. In slaughter establishments, the inspector shall tag a common area with a "U.S. Rejected" tag if the inspector finds a common area which is unsanitary. The inspector shall remove the "U.S. Rejected" tag after the common area is cleaned.

B. In slaughter establishments, if product contamination resulting from exposure to common areas is suspected or found, the inspector shall:

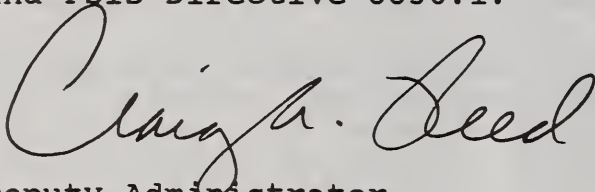
1. tag the common area with a "U.S. Rejected" tag,

2. tag and retain the carcasses or parts,

3. reinspect the carcasses or parts after the establishment has taken appropriate action acceptable to the inspector, and

4. remove the "U.S. Rejected" tag from the common area after the establishment has taken appropriate action acceptable to the inspector.

C. In processing establishments, if product contamination resulting from exposure to common areas is suspected or found, and/or unsanitary conditions are found, the inspector shall take corrective action as specified in FSIS Directive 8820.1, Rev. 1, and FSIS Directive 8830.1.

A handwritten signature in cursive script, reading "Craig A. Reed". The signature is written in dark ink and is positioned above the printed title.

Deputy Administrator
Inspection Operations